



Office of Pesticide Programs Annual Report for 1995



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NOTE:

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Foreword

EPA's Office of Pesticide Programs (OPP) is making significant progress in carrying out its important responsibilities — safeguarding public health and the environment from pesticide risks, and ensuring that pesticides are regulated fairly and efficiently. OPP's Fiscal Year 1995 achievements are especially noteworthy as they were accomplished while the program was engaged in extensive reinvention initiatives, planning for a major realignment, and responding to pressures and concerns about impending budget actions.

This was a banner year for both the registration and reregistration programs, with 40 new active ingredients registered and 40 Reregistration Eligibility Decisions (REDs) issued. To put these numbers in perspective, consider that historically, only about a dozen new active ingredients were registered annually. Dramatic improvements began to show in FY 1994, when 30 new active ingredients were registered. The upward trend continued in FY 1995, with a record-breaking 40 new registrations accomplished. Impressively, well over half of the new registrations during the past two years are for “safer” or reduced risk products, many with lower use rates than conventional pesticides, and 35 are biopesticides.

During FY 95, the timeliness of EPA registration decisions improved substantially. Historically, it has taken on average four to six years to register a new pesticide. During the past year, average processing times were reduced as follows: reduced risk pesticides (8-16 months); biopesticides (3-16 months); and all other new active ingredients (3-52 months).

OPP also accelerated its reregistration program for older pesticides, reaching its planned annual goal of 40 REDs in FY 95, for a grand total of 121 REDs. Combined with last year's total of 34 REDs, this means an impressive 74 reregistration decisions — two-thirds of all REDs issued — were accomplished in the last two years. These decisions were made following OPP's comprehensive review of literally thousands of scientific studies on the potential effects of pesticides and their fate in the environment. Based on this review, EPA took action to reduce pesticide risks by imposing many new requirements and restrictions as conditions of reregistration. While much work remains to be done, including REDs for many major pesticides with food-related uses, less than half of the original universe of older pesticides remain in the pipeline for review.

Beyond the registration and reregistration programs, EPA implemented a number of other initiatives to protect public health and the environment. OPP worked to serve all of its customers by responding to requests for information and managing the distribution of hundreds of thousands of EPA-produced documents that help ensure safer pesticide practices in the home, in schools, in agriculture, and in industrial settings. Notably, the Worker Protection Standard became fully effective in 1995. This standard ensures that over three million agricultural workers have the training and equipment they need to protect themselves from pesticide risks on the job. At the same time, EPA continues to work to refine its rules to ensure appropriate flexibility in implementation, and to focus resources on true public health and environmental problems, by streamlining and “deregulating” wherever possible and establishing new alliances, such as the Pesticide Environmental Stewardship Program.

A talented team of dedicated employees from across all OPP divisions made these accomplishments possible. In addition, EPA's partners in the regional offices and state and tribal pesticide regulatory agencies continue to play a key role in implementing and enforcing pesticide programs and policies. This Foreword highlights only a few of OPP's positive achievements over the past year. Others are described more fully in the following pages. The goal of the Annual Report is to provide a public accounting of our work for all of our constituencies. I hope that it will serve an important function in communicating the depth and breadth of OPP's responsibilities and accomplishments.

Daniel M. Barolo, Director
Office of Pesticide Programs

Introduction

Protecting public health and the environment from the risks posed by pesticides is a challenging and complex undertaking. By their very nature, pesticides create some risk of harm to humans, animals or the environment because they are designed to be biologically active and have a negative effect on living organisms. At the same time, pesticides are useful to society because of their ability to kill potential disease-causing organisms and to control insects, weeds, and other pests.

Over the past twenty years, EPA's Office of Pesticide Programs (OPP) has developed a number of programs structured to meet the challenge of evaluating and reducing pesticide risks and promoting safe pesticide use. These programs govern a wide variety of pesticide products and uses that are likely to be found in virtually every home and business in the United States — from insect repellents to weed killers to hospital disinfectants to swimming pool chemicals — to name a few. The health and environmental issues raised by pesticides in these many settings are varied and complex. In carrying out its responsibilities, OPP must consider both the need to minimize risks and the benefits that pesticides offer to society. State and tribal agencies and many other organizations, both public and private, are vital partners in this effort.

While it would take many more pages to fully depict the extensive efforts and achievements of this program, this report attempts to describe many of the accomplishments of the Office of Pesticide Programs during the 1995 fiscal year (October 1, 1994 to September 30, 1995).

Annual Report Structure

While OPP staff are formally organized into eight divisions and a policy staff, this report is organized around the six major activity areas used in the resource planning process. In addition, the seventh chapter discusses some other special initiatives.

1 - Registration

Making decisions about the registration (licensing) of individual pesticide *products*, and assuring that decisions are consistent and up-to-date.

2 - Reregistration

Bringing the scientific data base for older pesticide *active ingredients* up to current standards, reassessing their regulatory status, mitigating risks, and documenting new decisions. Assuring that products containing eligible active ingredients are supported by valid data, are labeled correctly, and are reregistered.

3 - Special Review

Conducting in-depth assessments of pesticides suspected of posing unacceptable risks to public health or the environment.

4 - Field Implementation and Communications

Working with EPA regional offices, states, and tribal organizations to implement pesticide programs, communicating with the public about pesticide issues, and supporting compliance efforts.

5 - Policy, Regulations, and Guidance

Developing pesticide policies and regulations, including improvement of the quality of scientific information used to make decisions.

6 - Information and Program Management

Managing pesticide information (including automated information systems, computers and computer networks, and paper and microfiche collections) and administering programs (including human resources, facilities, finances, and budget planning).

7 - Biopesticide, Risk Reduction, and Reinvention Initiatives

Though integrated into the other six areas for budget purposes, these initiatives are given special attention in this report. They involve encouraging the introduction of a new generation of biological pesticides, reducing pesticide risks through environmental stewardship, and reinventing OPP organizations.

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Chapter 1: Registration

This chapter describes the pesticide registration program, which provides the foundation for nearly all OPP activities. In addition to allowing the use of new pesticides, the registration program includes many activities related to the ongoing registration of existing pesticides, such as label changes in where and how they may be used in order to reduce risks or in response to requests by registrants. This chapter also describes several reinvention activities aimed at improving regulatory decisions, processes, and team structures. Also contained in this chapter are summaries of special programs ensuring the effectiveness of antimicrobial pesticides, improving pesticide labels, and the role of OPP's laboratories in pesticide registration.

Overview Of Registration

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires that before anyone can sell or distribute any pesticide in the United States, they must obtain a registration, or license, from EPA. The term pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and any substance or mixture intended for use as a plant regulator, defoliant, or desiccant. When making a pesticide registration decision, EPA must ensure that the pesticide, when used according to label directions, will not cause unreasonable adverse effects to human health or the environment.

Registration decisions are based primarily on EPA's evaluation of the test data provided by applicants. EPA has established a number of requirements, such as the Good Laboratory Practice Standards, that apply to both registrants and testing facilities to ensure the quality and integrity of pesticide data.

Depending on the type of pesticide, OPP can require more than 100 different tests. Testing is needed to determine whether a pesticide has the potential to cause adverse effects to humans, wildlife, fish, and plants, including endangered species. Potential human risks, which are identified using laboratory tests in animals, include acute toxic reactions (such as poisoning and skin and eye irritation) as well as possible long-term effects (such as cancer, birth defects, and reproductive disorders). Data on the fate of pesticides in the environment are also required so that OPP can assess threats to ground and surface water or other risks.

OPP processes a variety of registration applications, including: new pesticide active ingredients, new uses (applications for new uses of an already registered pesticide), "me-too's" (applications for registrations of pesticide products that are substantially similar or identical in their uses and formulation to currently registered products), and experimental use permits (which set specific terms under which prospective registrants may test pesticides outside of the laboratory prior to registration).

Under section 18 of FIFRA, states may apply to EPA for an exemption or declare a crisis exemption for emergency use of a pesticide not registered for that use. Four types of

emergency exemptions may be authorized. A *specific* exemption may be authorized in an emergency situation to avert significant economic loss, or significant risks to endangered species, beneficial organisms, or the environment. A *quarantine* exemption may be authorized in an emergency to control the spread of any pest new to or not known to be widely prevalent within the United States or its territories. An emergency *public health* exemption may be authorized to control a pest that will cause a significant risk to human health. In an emergency where there is not time to allow for EPA authorization of the applicable specific, quarantine, or public health exemption, a state may invoke a *crisis* exemption.

Under section 24(c) of FIFRA, states may issue registrations for additional uses of currently registered pesticides to meet special local needs.

New Registrations In 1995

1995 was a banner year for OPP with the registration of 40 new pesticide active ingredients, more than half of which are considered reduced risk pesticides, including biopesticides. Biopesticides include “microbial pesticides” (bacteria, viruses, or other microorganisms used to control pests) and “biochemical pesticides,” such as pheromones (insect mating attractants), insect or plant growth regulators, and hormones used as pesticides. Biopesticides generally pose less risk to human health and the environment than conventional chemical pesticides. Many of these reduced risk pesticides were submitted under the voluntary Reduced Risk Pesticides Initiative. The following table describes the pesticide active ingredients registered for the first time in fiscal year 1995.

New Pesticide Active Ingredients Registered in FY 1995

Pesticide Name	Registrant	Pesticide Type	Use(s)	Biopesticide or Other Reduced Risk Pesticide?
AO-159	DuPont	Insecticide	Pets, livestock	No
Bt Corn	Ciba Seeds and Mycogen	Plant-Pesticide	Field corn	Yes (biopesticide)
Bt Potatoes	Monsanto	Plant-Pesticide	Potatoes	Yes (biopesticide)
<u>Bacillus thuringiensis</u> subsp. <u>kurstaki</u>	EcoGen Inc.	Microbial insecticide	Potatoes, tomatoes, eggplants	Yes (biopesticide)
<u>Beauveria bassiana</u> Strain GHA	Mycotech Corp.	Microbial Insecticide	Various crops, rangeland, pastures	Yes (biopesticide)
<u>Beauveria bassiana</u> ATCC 74040	Troy Biosciences	Microbial Insecticide	Ornamental plants, turf	Yes (biopesticide)
<u>Candida oleophila</u>	EcoGen Inc.	Microbial fungicide	Citrus and pome fruits	Yes (biopesticide)
Celery Looper Virus	BIOSYS	Microbial insecticide	Vegetables	Yes (biopesticide)
Chlorethoxyfos	DuPont	Insecticide	Corn	No
<u>Cydia pomonella</u>	Louis Falcon	Microbial Insecticide	Fruits	Yes (biopesticide)
(E)-5-Decenol	Consep Inc.	Insect pheromone	Fruits, nuts	Yes (biopesticide)
(E)-5-Decenyl Acetate	Consep Inc.	Insect pheromone	Fruits, nuts	Yes (biopesticide)
Diethyl Sulfide	Bear Country Products	Deterrent	Bears	No
Difethialone	LiphaTech, Inc.	Rodenticide	Residential use	No
1,4 Dimethyl-napthalene	D-I-1-4 Inc.	Plant Growth Regulator	Potatoes	Yes
Diocetyl Sodium Sulfosuccinate	Safe and Sure Products	Insecticide	Pets	No
Fenbuconazole	Rohm and Haas Co.	Fungicide	Pecans	No
Flumiclorac Pentyl Ester (Resource)	Valent	Herbicide	Corn	Yes
Halosulfuron	Monsanto	Herbicide	Corn, ornamental plants	No
Hymexazol	Sumitomo Chemical	Fungicide	Seed treatment	Yes
Isobardac	Lonza, Inc.	Antimicrobial	Water treatment	No
Mattch Bt K	Mycogen	Microbial insecticide	Fruits	Yes (biopesticide)
Maxim	Ciba-Geigy	Fungicide	Seed treatment	Yes
Methyl Anthranilate	Dolphin Trust	Bird Repellent	Small fruits, ornamental plants	Yes

Pesticide Name	Registrant	Pesticide Type	Use(s)	Biopesticide or Other Reduced Risk Pesticide?
Neem Oil	W.R. Grace and Co.	Fungicide	Ornamental plants	Yes (biopesticide)
Poly (N,N-dimethyl diallyl ammonium chloride)	Calgon	Antimicrobial	Water systems	No
Potassium Bicarbonate (baking soda)	Church & Dwight Co.	Fungicide	(Retail pesticide products not yet approved)	Yes
Prallethrin	Sumitomo	Insecticide	Pets, residential uses	No
Primisulfuron Methyl	Ciba-Geigy	Herbicide	Corn	No
<u>P. syringae</u> ESC 10	EcoScience Corp.	Microbial fungicide	Fruits (post-harvest)	Yes (biopesticide)
<u>P. syringae</u> ESC 11	EcoScience Corp.	Microbial fungicide	Fruits (post-harvest)	Yes (biopesticide)
Pyridaben	Nissan Chemical	Insecticide	Ornamental plants	No
Pyriproxyfen	Mclaughlin Gormley King Company	Insecticide	Pets	No
Pyrithiobac-sodium	DuPont	Herbicide	Ornamental plants	No
Rimsulfuron	DuPont	Herbicide	Corn	No
Sodium Bicarbonate (baking soda)	Church & Dwight Co.	Fungicide	(Retail pesticide products not yet approved)	Yes
Sodium Carboxymethyl-cellulose	Creative Services Inc.	Insecticide	Ornamental plants	Yes
Sodium 5-Nitro-guaiacolate	Asahi Chemical Manufacturing	Plant Growth Regulator	Cotton, rice, soybeans	Yes
Tebufoenozide	Rohm and Haas Co.	Insecticide	Walnuts	Yes
Undecylenic Acid	Safe and Sure Products	Insecticide	Pets	No

Other 1995 Registration Achievements

Registering new pesticides for the first time is only one of an enormous number of pesticide registration actions that OPP carries out each year. Decisions made in 1995 are summarized in the following table. Both approvals and denials of the requests received by OPP are included in the number of decisions.

1995 Registration Activities

Registration Activity	Description of Activity	Number of Decisions
Registrations of new pesticides	First approval for use of pesticides not currently registered in the United States.	40
Additional registrations for previously registered pesticides	Registrations for new products containing pesticide ingredients already approved for proposed uses.	832
Amendments to existing registrations	Amendments, for example, to reflect revised labels and changed formulations for products already registered.	3,614
New uses for previously registered pesticides	Approvals for uses of a pesticide (such as on particular food crops) for which it has never been registered.	124
Emergency exemptions ("Section 18s")	Decisions on granting emergency exemptions to states or other federal agencies to allow use for a limited period of pesticides not registered for those particular uses.	400
Experimental Use Permits (EUPs)	Decisions on permits that allow pesticide producers to test new pesticide uses outside of the laboratory; generally required if more than 10 acres are involved in the proposed study.	100
Tolerances	Decisions on approving tolerances, or maximum allowable levels of pesticide residues in food or animal feed. Tolerances (or exemptions from tolerances) are required whenever a pesticide is registered for use on a food or feed crop.	122
Temporary Tolerances	Decisions on tolerances for experimental purposes for an unregistered pesticide.	34
Special Local Need Registrations ("Section 24(c)s")	Registrations of pesticide products by state agencies for specific uses not federally registered. (The pesticides must be federally registered for other uses.)	475

Reinvention/Risk Reduction Activities

Over the past several years, OPP has undertaken a major effort to overhaul its registration program, which in 1995 began to pay substantial dividends. The reinvention effort aims to accelerate the pace of decision-making and redirect staff activities to those most important in protecting health and the environment. This section describes the highlights of these initiatives.

Agreement with California to Harmonize Pesticide Regulation

OPP and the Department of Pesticide Regulation (DPR) of the California Environmental Protection Agency began an initiative in 1994 to harmonize and simplify pesticide registration, and to exchange work products to reduce duplication of effort and expense. The first major milestone of this initiative was the signing of a Memorandum of Understanding (MOU) in May 1994. During 1995, significant progress was made in achieving the objectives of the MOU. For example, OPP and DPR began sharing the workload of reviewing acute toxicology studies, thereby reducing review cost and time. This should help OPP continue to reduce its current backlog of pending acute toxicity submissions. OPP also identified products intended for registration under FIFRA as well as in California. Other ongoing cooperative activities include harmonization of risk assessment methods, international standards, and registration of new active ingredients.

Voluntary Reduced Risk Pesticide Initiative

Since the inception of this initiative in 1993, OPP has received 20 reduced risk pesticide applications. OPP has accepted nine candidates (registering six so far), denied seven candidates, and is considering four. OPP is committed to expedited review of reduced risk applications and to making a registration decision within one year after a candidate has been granted reduced risk status. OPP issued a draft Pesticide Regulation (PR) Notice expanding the initiative to include new uses of pesticides that have been granted reduced risk status, and expects to finalize the notice by December 1995.

Faster Approval of Minor Registration Changes

In May 1995, OPP took a major step in reducing its workload in reviewing minor registration changes by issuing PR Notice 95-2. The notice significantly expands the categories of minor changes, such as changes to labeling and packaging, that registrants can make without waiting for OPP approval. Under this program, OPP expects that as many as 500 amendments each year, or 10% of the total, will be made by notifying OPP rather than requesting approval. For certain cases of minor changes not expected to change the potential risks of the products, registrants are not even required to notify OPP of the changes. In addition, the notice creates an accelerated process for reviewing minor formulation changes in 45 days instead of 90 days. Besides reducing OPP's workload, this action will allow registrants to make changes much more quickly.

Exemption of Effluent Discharge Statements for Small Container Products

On May 1, 1995, OPP issued PR Notice 95-1 exempting small containers (less than five gallons liquid or 50 pounds dry weight) from previously-required effluent discharge labeling. This reduces the burden on small container products with labels that lack space for these statements. Effluent discharge statements continue to be required for larger containers used in the industrial/commercial sector.

Encouraging Water Soluble Packaging (WSP)

Water soluble packaging allows a pesticide product to be transferred from its original container to the tank from which it will be applied with a minimal risk of spills or splashes. It also eliminates the need for rinsing the original container. Because of these benefits to pesticide handlers and the environment, OPP began to implement a streamlined process for registering WSP products in 1995. Registrants who wish to market a registered product in water soluble packaging can do so using the same registration number and by notifying OPP rather than waiting for OPP approval.

Other Reinvention Initiatives in Progress

Other efforts to improve the registration process in 1995 included:

- ▶ Exploring the possibility of allowing registrants to self-certify the results of product-specific acute toxicity tests rather than requiring OPP review.
- ▶ Working to finalize a rule proposed in 1994 under section 25(b) of FIFRA that would exempt a number of pesticides from regulation because they do not pose risks warranting regulation.
- ▶ Developing guidance to standardize and simplify procedures for certain registration applications.
- ▶ Preparing a proposal to streamline the registration of different sizes of rodent control pesticide products.
- ▶ Developing a proposal to allow self-certification by registrants of certain “me-too” products.

Implementing Acetochlor Registration Conditions

In registering the pesticide acetochlor in 1994, OPP embarked on a new approach by setting strong standards to protect ground and surface water. The approach establishes clear criteria that trigger voluntary suspension or cancellation of the registration if water quality is adversely affected. In particular, the Acetochlor Registration Partnership (ARP) is required to

conduct extensive monitoring programs to ensure that use of this herbicide will not adversely affect ground or surface water.

During the past year, OPP worked with the partnership and State Lead Pesticide Agencies to implement the registration agreement. The ARP established 175 monitoring wells, 25 in each of the seven major use states (Illinois, Indiana, Iowa, Kansas, Minnesota, Nebraska, and Wisconsin). The ARP also established 175 surface water monitoring sites at drinking water supply facilities in 12 states, and began biweekly monitoring in March. Detections of acetochlor in ground water were reported in eight wells, which the ARP is investigating. Acetochlor was found in approximately 20% of the surface-water samples collected, generally well below the 2 ppb annual trigger. Also, the ARP began work on a second monitoring program, initiating two of eight prospective ground-water studies in Wisconsin and in Ohio. Four additional studies will begin in 1996, and the last two in 1997.

The Agreement between the ARP and OPP has already produced results. In the first year of use, the ARP has restricted the use of acetochlor on sandy soils to reduce the risk of ground-water contamination. OPP has validated the ARP's multi-residue method for detecting acetochlor and is reviewing the ARP's acetochlor-specific detection method. Finally, an ARP evaluation found that commercially available, low-cost methods may be useful in screening for the presence of acetochlor and similar compounds in water.

Recently, OPP made available to the public a map indicating areas throughout the country where acetochlor has been sold between March 1994 and January 1995. This county level usage information will be made available to the public annually by OPP and can be used to target monitoring by states and others.

Ensuring The Effectiveness Of Antimicrobial Pesticides

Antimicrobial products are used to control "germs" such as bacteria and fungi (molds and mildews) that can cause odors, food spoilage, or infections. They are used in homes, hospitals, cafeterias, restaurants, and many other institutions. Over the past several years, OPP has implemented a comprehensive strategy to ensure the efficacy of antimicrobial pesticides, placing highest priority on those that have significant public health uses. During 1995, OPP accomplished many of its research goals under a comprehensive Antimicrobial Program Strategy. Highlights include:

Test Methodology Research Cooperative Agreements

Substantial progress was made in each of the five research cooperatives. Three cooperatives finalized most of the research to improve the existing test methods used to determine antimicrobial product efficacy. New sporicidal, virucidal and tuberculocidal test methods have been developed and are in the process of being validated through collaborative studies. Another agreement focused on bacterial cell injury and proposed a protocol for determining the level of injury sustained during typical efficacy test conditions.

Antimicrobial Complaint System Cooperative Agreement

Through the National Pesticide Telecommunications Network (NPTN), the Antimicrobial Complaint System (ACS) handles phone inquiries and complaints regarding EPA-registered antimicrobials. The ACS responded to over a thousand calls in 1995.

Antimicrobial Product Testing Program

In 1995, the Antimicrobial Product Testing Program was converted from a contract to an OPP-managed program. Product efficacy testing of tuberculocides and hospital disinfectants is now being conducted at OPP's new Microbiology Laboratory in Cincinnati. The laboratory will continue to evaluate selected hospital disinfectant and tuberculocidal product claims in support of OPP's Testing Program to ensure the efficacy of antimicrobial pesticides. The laboratory will also assist in enforcement actions where efficacy claims cannot be confirmed.

Efforts To Improve Pesticide Labels

Labeling is one of OPP's most important tools for achieving its mission of protecting human health and the environment. No other pesticide document or publication has a more direct impact on risk reduction or the potential to prevent pollution. Over time, however, some labels have become cluttered and confusing. OPP has taken several steps to address labeling concerns and has accomplished the following:

Computer Software to Standardize Precautionary Labeling.

Precautionary statements are those portions of a pesticide label that summarize a product's hazards, provide first aid instructions, and list storage and disposal instructions. In 1995, OPP began developing a computer program which displays the correct precautionary labeling statements for a product based on acute toxicity studies. This system could be used by both OPP and registrants to assure accurate and appropriate precautionary labeling. This could help reduce review time and rejection of applications with incorrect labeling. OPP expects to distribute the software in early 1996.

Label Review Manual. In December 1994, OPP completed and made available its first comprehensive *Label Review Manual*, a document to be used by OPP staff in reviewing and determining the acceptability of pesticide labeling. The manual is available to the public.

Label Policy Directory. In October 1994, OPP launched an electronic "on-line" Labeling Policy Directory that allows OPP staff to quickly search and access labeling policy information via computer. Portions of the directory will soon be made available to the public.

Labeling Coordination. OPP issued a draft PR Notice establishing an annual compliance date for implementing most EPA-mandated labeling changes, and describing current approaches to coordinating labeling issues and related streamlining efforts. After review of public comments, OPP plans to issue a final notice in 1996.

Total Release Fogger Labels. OPP continued to work to improve the labels of total release foggers, sometimes called “bug bombs.” The aerosol propellants found in these indoor fumigants can cause fires or explosions if the products are not used properly. OPP expects to issue final labeling requirements in 1996.

Pesticide Chemistry Laboratory Support For Registration

OPP's pesticide registration program is supported by two pesticide chemistry labs: the Analytical Chemistry Laboratory (ACL) in Beltsville, Maryland, and the Environmental Chemistry Laboratory (ECL) in Bay St. Louis, Mississippi. The labs support registration through the food tolerance and environmental chemistry methods validation programs, which ensure that pesticide residues can be accurately measured in food and the environment.

The ACL has the lead responsibility for the food tolerance methods validation program. In fiscal year 95, ACL validated a record 65 food tolerance methods out of a total of 102 submitted or carried-over from 1994 (see figure on next page). In addition, the ACL developed a new method for detecting residues of multiple sulfonylurea pesticides in water using capillary zone electrophoresis. Scientists are enthusiastic about the method and additional work is underway at both EPA and industry labs to determine the suitability of the method for monitoring pesticide residues.

The ECL has lead responsibility for the environmental chemistry methods validation program. The demand for environmental chemistry methods testing increased dramatically in 1995 (see second figure on next page). The primary emphasis of this program is to evaluate those methods associated with studies for environmental fate, exposure, and ecological effects. The ECL completed 35 validations in 1995, including three expedited methods for acetochlor. ECL continued to evaluate new, low-cost technology for detecting pesticide residues using immunoassay tests, completing review of eight tests in 1995.

Tolerance Method Validations

	FY 91	FY 92	FY 93	FY 94	FY 95
Carried-over Requests	7	6	7	9	23
New Requests	26	18	31	63	79
Completed	27	17	29	49	65

Environmental Chemistry Method Validations

	FY 91	FY 92	FY 93	FY 94	FY 95
Carried-over Requests	0	3	9	17	23
New Requests	6	10	16	17	54
Completed	3	4	8	11	35

Chapter 2: Reregistration

Pesticide reregistration is one of OPP's most vital programs. OPP is required by 1988 amendments to federal pesticide law to review and, as warranted, reregister all existing pesticide products that contain active ingredients initially registered before November 1, 1984. The goal is to update labeling and use requirements and reduce potential risks associated with older pesticide active ingredients — those first registered when the standards for government approval were less stringent than they are today. This comprehensive reevaluation of pesticide safety in light of current standards is critical to protecting human health and the environment.

This chapter discusses OPP's progress in reregistering pesticides, as well as some related initiatives. These include efforts to develop additional information on pesticide exposure to people who enter treated lawn and turf areas and to reduce the risks posed by pesticide spray drift.

Steps In Reregistering Pesticides

Through the pesticide reregistration program, now in its final phase, OPP is reviewing studies submitted to support each reregistration case (or group of related pesticide active ingredients). After examining the health and environmental effects, OPP employs measures to mitigate risks most effectively. This evaluation and risk mitigation process is complete when OPP is satisfied that the pesticide, used in accordance with approved labeling, will not pose unreasonable risks to human health or the environment.

OPP's regulatory conclusions about each case are presented in a Reregistration Eligibility Decision document, or RED. Later, once product-specific data and revised labeling are submitted and approved, OPP reregisters products containing the eligible pesticide(s). A product is not reregistered, however, until all of its active ingredients are eligible for reregistration.

1995 Reregistration Progress

OPP is making significant progress in reregistering pesticides. During fiscal year 1995, OPP completed 40 Reregistration Eligibility Decisions, or REDs, a record in terms of both the number and magnitude of the decisions. Working with the Special Review program (described in chapter 3), the reregistration program is employing a variety of measures to reduce the most serious pesticide risks. These include use phaseouts, voluntary cancellations, restricted use classifications, ground-water label advisories, and strengthened requirements to better protect pesticide handlers and other workers. New label guidance for aerial applications, requirements for vegetative buffer strips bordering areas treated with pesticides, and reduced application rates are reducing risks to wildlife.

For example, the Picloram RED Team worked with state representatives and the registrant to reduce use rates in order to decrease risks to nontarget plants. The Ethalfluralin

RED Team strengthened personal protective equipment and restricted entry intervals to reduce risks of cancer and developmental effects to workers, and required buffer strips to mitigate threats to aquatic wildlife.

With this year's accomplishments, OPP has completed a total of 121 REDs covering 30 percent of the cases to be reregistered, including glyphosate, metolachlor, picloram, and other major pesticides. About 1,000 tolerances (maximum legally permissible levels of pesticide residues in foods) have been reassessed, and many are being revised to better ensure food safety. About 750 products have completed the process and have been reregistered.

Looking to the future, more pesticides with food uses and other significant human exposures are scheduled for reregistration eligibility decisions during fiscal year 1996. For the first time, OPP expects that the number of candidates ready for decisions in FY 1996 will exceed the resources available to complete those decisions.

Some of the principal accomplishments of the reregistration program during fiscal year 1995 and cumulatively are summarized below.

Annual and Cumulative Completion of REDs

The number of REDs completed per fiscal year has been increasing steadily since the accelerated reregistration program began. This number reached 40 in fiscal year 1995 for a cumulative total of 121 completed REDs. A target of 40 more REDs has been set for 1996.

Number of REDs Completed:

FY91:	13
FY92:	15
FY93:	19
FY94:	34
FY95:	40
Cumulative through FY95:	121
FY96 Goal:	40
FY96 Cumulative Goal:	161

Status of Reregistration Cases

OPP has completed a total of 121 REDs, representing nearly one third of the 382 chemical cases currently supported for reregistration. Meanwhile, 230 of the original 612 cases are unsupported (meaning that the registrants have decided not to complete and submit the studies required for reregistration). Cases that remain unsupported have been or will be cancelled. OPP therefore has 261 more REDs to complete, less than half of the original cases from 1988.

Anatomy of the 121 REDs Completed

...Or, What “121 REDs Completed” Means...

The 121 REDs completed cover 170 pesticide active ingredients, 4,633 products, and 957 tolerances. They represent about 30% of all supported reregistration cases (a case consists of one or more related pesticide active ingredients); 30% of all food use pesticides (supported List A cases); and 17% of original List A tolerances reassessed.

As described in the table below, the completed REDs represent about two-thirds of the total quantity of pesticides used (by volume) in the United States. They include over two-thirds of all homeowner-applied pesticides, about one third of all pesticides used in agriculture, and two-thirds of all pesticides used commercially, by industry and government.

Amount of Pesticide Usage (by Volume) Covered By REDs Completed*

	Homeowner Applied	Agriculture	Commercial/ Industrial and Government	TOTAL
Fungicides	50% to 55%	60% to 65%	4% to 7%	40 to 48%
Herbicides	20% to 25%	30% to 35%	16% to 30%	28 to 32%
Insecticides	10% to 15%	1% to 2%	3% to 5%	8 to 10%
Antimicrobial s	99% +	99% +	99% +	99%
TOTAL	68%	32%	65%	65%

* Please note that the REDs completed for two antimicrobial cases — bleach (sodium and calcium hypochlorite) and chlorine — account for a large proportion of the usage of antimicrobials and the overall usage of pesticides covered by the REDs completed so far. Note, too, that the pounds used may not indicate the relative percent of market share or number of applications.

REDs Completed in 1995

The following table summarizes the 40 REDs completed in FY 1995:

Pesticide Case	Pesticide Type	Use(s)	Eligible for Reregistration?
<u>Agrobacterium radiobacter</u>	Fungicide Insecticide	Fruit, nut, and ornamental trees (nursery stock)	All uses
Aliphatic Alcohols (ethanol and isopropanol)	Antimicrobial Fungicide Insecticide Plant Growth Regulator	Indoors (including homes), agriculture	All uses
Alkyl Imidazolines	Antimicrobial	Fuel oil	All uses
Amitraz	Insecticide	Cotton, pears, livestock, dogs	All uses
Ancymidol	Plant Growth Regulator	Ornamental plants	All uses
Asulam	Herbicide	Sugarcane, ornamental plants, turf, other non-cropland uses	Some uses
Benzocaine	No longer considered a pesticide	Medicine (regulated by Food and Drug Administration, not EPA)	(Not applicable)
O-Benzyl-Chlorophenol	Antimicrobial	Various indoor uses, including agricultural, food, and medical facilities	All uses
Bis(trichloromethyl)sulfone	Antimicrobial	Water systems, industrial uses, chemical products	Some uses; one use awaiting additional information
Bromohydroxyacetophenone (BHAP)	Antimicrobial	Paints, adhesives, and other chemicals	All uses
Bronopol	Antimicrobial	Water systems, industrial uses, chemical products	All uses
Chlorhexidine Diacetate	Antimicrobial	Livestock facilities	All uses
Chlorpropham	Herbicide Plant Growth Regulator	Potatoes, spinach, ornamental plants	Some uses; others awaiting additional information
4-Chlorophenoxyacetic Acid (4-CPA)	Plant Growth Regulator	Food industry (bean sprouts)	All uses
Cyanazine	Herbicide	Corn, cotton, sorghum	No: uses are being phased out
Cytokinin	Plant Growth Regulator	Various crops, ornamental plants, forestry	Some uses; others awaiting additional information
DCPA	Herbicide	Various crops, ornamental plants, lawns	All uses
Dimethoxane	Antimicrobial	Industrial uses, chemical products	All uses

Pesticide Case	Pesticide Type	Use(s)	Eligible for Reregistration?
Diquat Dibromide	Herbicide	Potatoes, seed crops, non-crop areas	All uses
Dowicil 100	Antimicrobial	Industrial uses, paint, textiles	All uses
Ethalfuralin	Herbicide	Various of vegetable and grain crops	Some uses; others awaiting additional information
Ethephon	Plant Growth Regulator	Cotton, various other crops, ornamental plants	All uses
Fenitrothion	Insecticide	Ornamental plants, greenhouses, indoors (including homes)	Some uses
Fosamine Ammonium	Herbicide	Rights-of-way, industrial sites, fencerows	Some uses
Linuron	Herbicide	Soybeans, other crops, ornamental plants	Some uses
Methyl Nonyl Ketone	Animal and Insect Repellent	Residences, ornamental plants	All uses
Metolachlor	Herbicide	Various crops, lawns, ornamental plants, rights-of-way, forestry	Some uses
Nabam	Antimicrobial	Water systems, other industrial uses	All uses
Nuranone	Insect (Japanese beetle) Pheromone	Agricultural and ornamental plants	All uses
Picloram	Herbicide	Rights-of-way, forestry, rangelands, pastures, small grain crops	All uses
Polybutene	Bird and Squirrel Repellent	Roosting sites, other indoor and outdoor locations	All uses
Prometryn	Herbicide	Celery, cotton, dill	All uses
Propamocarb	Fungicide	Ornamental plants, lawns, turf, golf courses	Some uses
Sodium Fluoroacetate (1080)	Predator (coyote) Poison	Sheep, goats	All uses
Sodium Omadine	Antimicrobial	Industrial uses, chemical products	All uses
Starlicide	Bird Poison	Bird feeding and roosting areas	All uses
Terbuthylazine	Algicide Antimicrobial	Water systems, fountains, aquaria	All uses
Tetrachlorvinphos	Insecticide	Livestock, pets, various other sites	Some uses
Trichlorfon	Insecticide	Various crops, other indoor and outdoor sites	Some uses
Trifluralin	Herbicide	Various crops, ornamental plants	Some uses

Risk Reductions Achieved Through FY 1995 REDs

The 1995 REDs include many changes intended to reduce risks to people and the environment. Some of the risk reduction measures achieved in the 40 REDs completed this fiscal year are summarized in the following table:

Number of REDs	Risk Reduction Measures Required By RED
2	Voluntary cancellation of all or many uses. (Cyanazine voluntary cancellation of all production for domestic use effective 12/31/99; use of existing stocks will be phased out in stages, and entirely by 1/1/03. Fenitrothion voluntary cancellation of all uses except ant & roach bait treatments.)
14	Some uses deleted or not currently eligible for reregistration.
5	Restricted Use Pesticide classification added or maintained, so that the pesticide may be used only by or under the direct supervision of a certified applicator.
27	Personal Protective Equipment (PPE) requirements for pesticide applicators strengthened or confirmed.
21	Restrictions that limit entry of workers into treated areas (including Restricted Entry Intervals/REIs) strengthened or confirmed.
19	Amount, frequency, or rate of application is reduced, limited, or specified.
40	Use Directions on labeling strengthened or made more specific, or Application Restrictions imposed.
25	User safety measures required.
10	Label Advisory or other measures to protect ground or surface water required.
18	Environmental Hazard statements to reduce ecological risks strengthened.
12	Tolerances revised (reduced, revoked, or newly approved).

Tolerances Reassessed

As part of reregistration, OPP is reassessing pesticide tolerances, or maximum residue limits in food and feed. A pesticide must have a tolerance (or be granted an exemption from the tolerance requirement) for each different type of food or animal feed on which it may be used. The number of tolerances for the List A pesticides (which represent the most significant food use pesticides) was about 5,600 in November 1988, when the accelerated

reregistration program began. Since then, almost 1,000 (or 18%) of the List A pesticide tolerances have been reassessed as part of the reregistration process.

Several hundred more tolerances are associated with List A active ingredients no longer supported for reregistration. These active ingredients ultimately will be cancelled and their tolerances revoked. Meanwhile, OPP is actively revoking tolerances as warranted by the tolerance reassessment decisions reflected in the REDs.

Status Of Studies Received

Registrants have responded to Data Call-Ins and other requirements by submitting over 20,000 studies in support of reregistration. Reviews of these studies provide the basis for OPP's reregistration decisions. By end of fiscal year 1995, OPP had reviewed almost 13,000 of these studies, including over 7,000 of the 9,500 studies received for List A pesticides. The cumulative numbers of studies received, reviewed, and awaiting review by scientific discipline are shown in the following figures for the List A pesticides and for all pesticides undergoing reregistration.

Study Review Status For List A Pesticides

Study Type	Received	Reviewed	Awaiting Review
Residue Chemistry	2,962	2,309	653
Environmental Fate	2,242	1,440	802
Reentry Non-Dietary	214	59	155
Toxicology, Non-CORT**	1,580	1,278	302
Toxicology, CORT*	766	684	82
Ecological Effects	1,822	1,483	339
All Disciplines	9,586	7,253	2,333

**Study Review Status For All Pesticides
Undergoing Reregistration (Lists A, B, C, and D)**

Study Type	Received	Reviewed	Awaiting Review
Residue Chemistry	4,760	3,102	1,658
Environmental Fate	3,916	2,194	1,722
Reentry Non-Dietary	283	67	216
Toxicology, Non-CORT**	5,292	3,061	2,231
Toxicology, CORT*	1,913	1,238	675
Ecological Effects	4,529	3,249	1,280
All Disciplines	20,693	12,911	7,782

- * Tox., CORT - Chronic feeding, carcinogenicity (oncogenicity), reproduction, and developmental toxicity (teratology) studies.
- ** Tox., Non-CORT - Studies other than CORT studies that measure the toxicity of pesticides.

Product Reregistration

While REDs are OPP's major reregistration output, much of the real world impact of eligibility decisions and risk reduction measures occurs after the RED is issued, once *products* are reregistered. As of October 1995, about 2,200 products have completed this concluding phase. OPP has reregistered about 750 of these products, granted 1,175 voluntary cancellations, amended 20 existing registrations, and suspended 300. An additional 600 products have just entered this phase, and decisions are pending on another 1,750. Activity in this important area is increasing rapidly and will accelerate during the next several years.

Product Reregistration Status

Status of Products	Number of Products
Reregistered	747
Amended	20
Canceled	1,175
Suspended	300
Pending	2,392
TOTAL	4,634

Process Improvements

Some innovations that have helped improve OPP's reregistration and Special Review processes and products during FY 1995 include the following:

SRRD Peer Review Committee — The Special Review and Reregistration Division (SRRD) Peer Review Committee, comprised of both staff and managers, is reviewing draft RED documents and Special Review Position Documents (PDs) to ensure clarity and consistency in addressing risk and regulatory issues.

Policy Capture Workgroup — This workgroup is developing a means of capturing electronically the issues addressed, policies established, and risk mitigation measures required by key regulatory decisions, primarily REDs and Special Review Position Documents.

RED Process Improvement Committee — This committee developed “A ‘How to’ Guide for REDs” providing guidance on RED schedules, team responsibilities, and meetings.

RED Document Improvement Workgroup — This workgroup is considering new, more comprehensible ways to present and disseminate the large body of information currently contained in a complete RED document package.

Pesticide Use and Usage Data Outputs — OPP is improving the compilation of pesticide use and usage information by consolidating information into a single database. While still in the developmental stage, it has already provided efficiencies by allowing quick access

to a preliminary overview of pesticide use parameters. In a related effort, OPP is piloting a new matrix format to provide key pesticide usage parameters to be used in the development of REDs. These efforts will continue to be refined.

Assessing Exposure to Turf Pesticides

OPP began a cooperative effort in 1995 with 35 pesticide manufacturers (the Outdoor Residential Exposure Task Force), California EPA, and Health Canada to obtain information on exposure to applicators and residents from pesticides used on home lawns. In March, OPP issued a Data Call-In for data which will be used to evaluate exposure to pesticides undergoing reregistration, as well as new pesticides being registered for the first time. The goal of the effort is to develop generic exposure data for different types of pesticide formulations so that exposure to lawn-care pesticides can be predicted without requiring data on specific compounds. This effort will save industry and OPP time and resources. Since the project is a joint effort with California and Canada, the findings from the required studies will be used to support pesticide registrations by their respective regulatory agencies as well. OPP expects the task force to begin submitting its initial findings in 1997 and to complete the effort in 1999.

Pesticide Chemistry Laboratory Support For Reregistration

In addition to supporting the pesticide registration program, as described in chapter 1, OPP's pesticide chemistry labs provide reregistration support. The labs work to confirm that the methods described by registrants for detecting pesticide residues in food and in the environment are effective. The Analytical Chemistry Laboratory (ACL) received 23 requests to validate food tolerance methods for reregistration in 1995, a marked increase from the seven requested in 1994, and validated nine methods. The Environmental Chemistry Laboratory (ECL) completed 20 analytical method validations for pesticides in soil and water under the reregistration program in 1995.

Reducing Pesticide Spray Drift

Aerial or ground application of pesticides may lead to off-target drift and result in exposure to workers, nearby residents, nontarget plants, and other ecological resources. During 1995 OPP continued its work with the Spray Drift Task Force (SDTF), an industry consortium conducting research into the factors which contribute to and can control spray drift. During 1995, the task force submitted its research results to OPP. OPP began a comprehensive scientific review of the data in 1995 and the review will continue during 1996.

In 1995, OPP continued its work with EPA's Office of Research and Development to develop computer models which will estimate the potential for off-target pesticide drift and suggest methods for reducing drift. Also, in conjunction with the SDTF and following input from some state and pesticide applicator groups, OPP developed a set of Best Management Practices (BMPs) for aerial pesticide application. During 1995, the BMPs were added to REDs, new chemical registrations, and other OPP actions involving aerial pesticide applications.

Chapter 3: Special Review

Special Review is EPA's formal process for determining whether the use of a pesticide poses unreasonable risks to people or the environment. In making this determination, EPA must consider the pesticide's risks and benefits. Special Review is designed to allow formal public input to the decision-making process. A Special Review can result in a decision to cancel, restrict, or continue the pesticide uses in question.

The Special Review process is set in motion when EPA has reason to believe that the use of a registered pesticide poses significant risks to people or the environment. Over 100 pesticides or groups of closely related pesticides have been evaluated through Special Review. While reregistration applies to all older pesticides, Special Reviews apply to those pesticides of particularly serious concern.

1995 Formal Special Reviews And Follow-up Activities

Triazines and the Cyanazine Phaseout

OPP initiated a Special Review for these related herbicides in November 1994. Up to 121 million pounds of atrazine, cyanazine, and simazine are used yearly on food crops including corn, and on cotton and turf. Atrazine currently is one of the two most widely used agricultural pesticides in the U.S. (based on pounds of active ingredient applied per year) and cyanazine ranks among the top five agricultural pesticides. In initiating the Special Review, the Agency determined that the triazines may pose significant risks of cancer due to exposure to residues in food and drinking water and through exposure when mixing, loading, and applying these pesticides. Growers, professional agricultural and lawn care applicators, and some homeowners appear to be at risk from using one or more of these products. OPP is also concerned about the risks to the environment from the large amount of triazines used.

Because each of the three pesticides appear to have similar potential to cause adverse effects, and because they can be used to some degree interchangeably, OPP decided to address their risks simultaneously. The announcement of the Special Review prompted over 87,000 public comments, all of which have been screened. The substantive comments are now being evaluated. The Agency's risk and benefit analyses, including responses to the comments, should be published by the end of 1996.

In August 1995, the primary registrant, DuPont, agreed to completely phase out production of cyanazine for domestic use and to voluntarily cancel its registration effective December 31, 1999. (The other formulator of cyanazine is now compelled to follow suit). Use of remaining stocks will be allowed through 2002, but maximum use rates will drop incrementally in 1997, 1998, and 1999. OPP believes that a significant reduction in potential risks from exposure to cyanazine will result from these reductions in cyanazine production and use. Additionally, beginning in 1998, all applications must be made from within a closed cab (meaning that the driver of the vehicle applying the pesticide is enclosed in a cab designed to

significantly reduce the exposure to pesticides being applied). The Agency expects to terminate the Special Review of cyanazine in 1996.

Lindane

In March 1994, the Agency proposed not to initiate a Special Review of lindane. The proposal was prompted by a review of studies in which laboratory animals were exposed to this organochlorine insecticide. Initially, OPP was concerned about risks to humans based on an effect on kidney function in male rats; the kidney effect is a serious and uncommon one that is usually associated with exposure to petroleum products. Further research showed that the lindane effect was particular to male rats, not female rats or any other species tested, and unlikely to occur in humans. OPP formally closed the Special Review for kidney effects in July 1995. Comments on the 1994 proposal, however, identified lindane as a potential disrupter of the endocrine system, so the Agency is now developing a strategy for evaluating that effect in lindane and three other organochlorine pesticides that are candidates for reregistration.

Propoxur

In January, the Agency proposed not to initiate a Special Review of propoxur, an insecticide once suspected of posing an unreasonable cancer risk to residents and pest control professionals. Propoxur is used to control indoor pests such as ants and cockroaches and also to control fleas on pets. In its proposal, OPP reported that the cancer risk has diminished since the Special Review was first suggested in 1988 because the registrants voluntarily dropped the uses which caused the greatest concern. OPP also reported that a reevaluation of exposure data and the cancer potency of propoxur indicated that the remaining uses are likely to present only negligible risks. OPP expects to complete its review of comments and issue a final decision in FY 1996.

Carbofuran

The uses of granular carbofuran on corn, sorghum, and rice were marked for phaseout by 1994 because of risks to wildlife, which were substantiated by large and widespread bird kills in and around treated fields. Birds of prey (such as eagles), waterfowl, game birds, and songbirds were all affected. The registrant appealed the decision, and in March 1995, the Agency rejected the reinstatement of uses on corn and sorghum while extending the use on rice for two years. The rice decision was based on a continued lack of alternatives to control the rice water weevil, a serious rice pest, and on the vigorous approach rice growers took to adopt environmental stewardship practices to protect wildlife at risk. These practices included working with the State of California and other agencies to identify and avoid times and sites where carbofuran application poses the greatest risk to threatened species, such as the bald eagle and the giant garter snake. The rice growers organization also supported a user education program and the development of publications for the program. The Agency is currently negotiating with the registrants of liquid carbofuran formulations to mitigate wildlife risks.

Dichlorvos

OPP issued a proposal to minimize the cancer and neurological risks of the insecticide dichlorvos (DDVP) in September 1995. Dichlorvos is used to control pests in the home, on livestock and manure, and in warehouses. The Agency is proposing to cancel some uses of dichlorvos, including all residential uses and use on stored food. Additional uses could be cancelled unless certain changes, such as restrictions on reentry into treated areas and prohibition of use except by licensed applicators wearing protective clothing, are incorporated into product labels. Public comment on the proposal will be accepted for 90 days.

Limited Reintroduction Of Aldicarb Use On Potatoes

When excessive residues of aldicarb appeared on potatoes in 1990, the Agency halted its sale and use in potato production. In September 1995, the Agency reapproved this use for farmers using positive displacement equipment — a new technology designed to control application rates more precisely and prevent spills and leaks. Use on potatoes is permitted only in Oregon, Idaho, Washington, Montana, northern Florida, and parts of Utah and Nevada, where the risk of ground-water contamination is believed to be low. Several other measures to reduce risks have also been imposed: furrow irrigation is prohibited; use after planting is prohibited; and the minimum interval between aldicarb application and potato harvest has been extended from 90 days to 100 days in Florida and 150 days elsewhere. Additionally, anyone wishing to apply aldicarb must receive special training in product stewardship. The reinstatement of use on potatoes is supported by data from the registrant showing that residue levels under the new application technology are within safe limits. Federal agencies will continue to monitor potatoes for aldicarb residues. The Special Review of aldicarb on the issue of ground-water contamination is still proceeding.

Chapter 4: Field Implementation and Communication

The first three chapters of this report have focused largely on OPP's work to ensure that individual pesticides are appropriately licensed, that decisions are made in a timely manner, and that the conditions of registration reflect up-to-date scientific standards. This chapter turns to the important area of field implementation and communication: OPP's work with pesticide users and others to ensure safe pesticide use practices are implemented in the field and to provide organizations and individual citizens with the information they need to make environmentally sound pesticide decisions. These efforts complement the pesticide regulatory programs described in the first three chapters and are critical to achieving our nation's health and environmental protection goals.

A. Field Programs

OPP managed four major field programs in FY 1995. These programs are aimed at protecting agricultural workers, endangered species and ground water from pesticide risks, and ensuring that applicators of potentially more hazardous pesticides are appropriately trained and certified in their use. In all of these programs, OPP relies heavily on cooperative relationships with regional offices, state and tribal pesticide regulatory agencies, other public and private organizations, and individuals. Only through the combined efforts of all of these groups can EPA's field programs be successfully implemented.

Implementing The Worker Protection Standard

OPP's Worker Protection Standard (WPS) for agricultural pesticides became fully effective on January 1, 1995. The Standard represents a major strengthening of national efforts to safeguard agricultural workers. It requires agricultural employers to ensure that employees receive basic training in pesticide safety and to notify workers when pesticides are applied. Employers also must provide washing facilities and supplies if workers are likely to come into contact with pesticides, and provide and maintain protective equipment to reduce potential health risks due to pesticide exposure in agriculture. OPP believes that effective implementation of the WPS will substantially reduce the risk of pesticide poisonings among agricultural workers and pesticide handlers.

In 1995, OPP carried out a number of WPS activities in collaboration with EPA's ten regional offices. In addition, OPP continued to refine requirements to maximize effective protection for workers in a wide variety of agricultural settings, while ensuring appropriate flexibility in implementation. Highlights of OPP's 1995 efforts include:

- ▶ Ongoing work with pesticide registrants to ensure that the labeling of all agricultural pesticides was revised to convey stronger worker protection requirements, such as restrictions on entry into treated areas and use of personal protective equipment. The goal of ensuring that all end-users received the required WPS labeling by October 1995 was achieved, without creating undue burdens on the pesticide industry.

- ▶ Work with the states, USDA's Cooperative Extension Service, and the agricultural community to help employers obtain the information and assistance they need. OPP created or funded 1,100,000 grower compliance manuals, 2,700,000 safety training manuals, 685,000 safety posters, 11,500 safety training videos, and 6,000 grower compliance video/slide sets that were made available free or at low cost to farmers and farmworkers.
- ▶ Implementation of a voluntary program to issue training verification cards to agricultural workers and pesticide handlers upon completion of WPS training. This will promote safety training and help agricultural employers fulfill their responsibilities by making it easier for them to verify that their workers have been trained. To date, 2,500,000 training verification cards have been distributed to the 42 states, Puerto Rico, and two tribes participating in the program.
- ▶ Workshops, periodic meetings, and ongoing discussions with agricultural groups and farmworker organizations affected by the WPS. These discussions enabled OPP to identify key concerns, resolve problems and improve implementation.
- ▶ Implementation of a process for considering requests for exceptions to WPS requirements. Under the WPS, OPP may approve exceptions if the benefits outweigh the costs (including any health risks attributable to the exception). In 1995, OPP denied an exception to the WPS early entry restrictions for uses of chlorothalonil in certain states, because the information supplied to OPP did not justify the exception.
- ▶ Issuing several final rules that strengthened WPS safety training requirements, but reduced certain requirements in situations where the restrictions were not necessary to achieve WPS objectives. For example, OPP reduced requirements for crop advisors who have already been through comprehensive training, for irrigation activities and other work that results in only limited contact with pesticides, and for situations involving use of relatively low risk pesticides.

Endangered Species Protection Program

The primary goal of OPP's Endangered Species Protection Program (ESPP) is to protect federally listed threatened and endangered species from the direct and indirect impacts of pesticide use, while minimizing regulatory burdens on pesticide users. OPP's current ESPP is an interim non-regulatory program. A final program will be established that reflects any necessary changes once Congress enacts legislation reauthorizing the Endangered Species Act.

During this interim period, the ESPP relies primarily on the development and dissemination of county-specific pamphlets that describe voluntary measures pesticide users can take to avoid affecting endangered species. In 1995, OPP began developing the pamphlets internally, ending dependence on contractors. A total of 277 pamphlets have been completed and are being distributed with state assistance in 25 states and Puerto Rico. OPP also

developed additional fact sheets on endangered species in FY 1995, bringing the total to 59, and continued to operate a toll-free endangered species hotline.

In implementing the ESPP, OPP works closely with EPA regions, states, and other federal agencies. The ESPP allows states to develop plans to protect species in their states in a manner suited to local conditions. At present, 20 states have developed plans, which may include detailed assessments and site-specific protection measures as well as provisions for agreements with landowners to protect species on their property. During 1995, OPP completed a status review of the plans, and (working with the U.S. Fish and Wildlife Service) approved the first two, prepared by North Dakota and Kansas. Several other states are close to approval.

Other FY 1995 highlights include:

- ▶ Continuing cooperative efforts with the Wyoming Department of Agriculture, U.S. Fish and Wildlife Service (FWS), and EPA's Region 8 to locate and protect the Wyoming toad. Local landowners again agreed to delay pesticide applications until their lands were searched for the presence of toads. Although reintroductions of this endangered species are being made in wildlife refuges, it appears that the toad no longer exists elsewhere in the wild, and all of the searched lands were cleared for pesticide use.
- ▶ Initiation of efforts to clarify the roles of OPP and federal land management agencies to protect species. Procedures have been worked out with the National Park Service and are being developed with the Department of Defense and the U.S. Forest Service.
- ▶ Cooperation with pesticide manufacturers, who have formed a task force to provide extensive and valuable information about where endangered species are located, relative to pesticide use sites on private lands.
- ▶ Verification with the FWS of the accuracy of OPP's comprehensive national database of the county-by-county location of endangered species. This database is available to other EPA offices and federal agencies, and to the public upon request.

Protecting Ground Water

Protection of ground water from pesticide contamination is the focus of OPP's third major field program. Ground water is a priority concern for both human health and environmental protection reasons. It is the source of drinking water for about half of the U.S. population, and because it flows into lakes and rivers it helps supports fish and wildlife habitats and commercial activity.

The centerpiece of OPP's ground-water strategy is a cooperative effort with the states and EPA regions to develop State Management Plans (SMPs) to prevent ground-water pollution from pesticides. Forty-eight states have submitted draft "generic" SMPs, designed to

create capacity for protecting ground water regardless of the particular pesticides used. The other two states are developing pesticide-specific plans in lieu of a generic plan. In 1995, EPA regions concurred (with comments) on three of the state plans, and are expected to concur on the remaining plans by the end of 1996. In 1995, OPP completed much of the work on the next major step, a proposed rule requiring SMPs for five widely-used herbicides frequently detected in ground water. OPP consulted extensively with state officials during 1995, so the proposed rule is expected to have broad support among the states when published for comment in 1996.

Another important feature of OPP's strategy has been to evaluate a pesticide's potential to contaminate ground water whenever OPP makes registration and reregistration decisions, with an emphasis on early mitigation of ground-water risks, as first implemented in 1994. The Agency is also continuing to track evidence of ground-water contamination through its Pesticides in Ground Water Database. In 1992, the Agency proposed a rule to establish specific criteria for classifying a pesticide as "restricted use" if any of its ingredients has the potential for contaminating ground water on a widespread basis. Restricted use pesticide products may be purchased and used only by certified pesticide applicators or individuals under their supervision. OPP believes that these specialized requirements will reduce the potential for ground-water contamination. In 1995, OPP completed much of the work on the final rule, which will be published in 1996.

Certification And Training Of Pesticide Applicators

When OPP designates some or all uses of a pesticide as "restricted use," then the pesticide may only be used by or under the direct supervision of specially trained and certified applicators. Certification programs are conducted by states, territories, and tribes in accordance with national standards set by OPP. All states require commercial applicators to be recertified, generally every three to five years, to maintain their certification. States also sometimes require recertification or other training for private applicators.

Over one million applicators are currently certified nationwide, including over 900,000 private applicators and about 350,000 commercial applicators. In 1994, the most recent year for which figures are available, more than 80,000 private and 60,000 commercial applicators were certified. More than 120,000 private and 120,000 commercial applicators were recertified in the same year. In addition, several hundred thousand applicators attended training sessions to learn or review appropriate methods for applying pesticides, in some cases as part of receiving or maintaining certifications.

In FY 1995, OPP continued work to revise national standards to better ensure continued competency of certified applicators. To assist state, territorial and tribal governments in conducting certification programs, OPP also funded 64 cooperative agreements and provided support to state extension coordinators through the U.S. Department of Agriculture. Other activities included support for train-the-trainer and pesticide applicator workshops; development of training materials on improving pesticide drift management and

application technology; and methods for evaluating behavioral and attitudinal changes in applicators as a result of certification and training programs.

B. Communications, Public Response, and Coordination

Few organizations serve a wider “public” than OPP. Communications efforts must be tailored to the needs of a broad spectrum of constituents who are affected by or interested in OPP actions and policies: other EPA offices and regions, state and tribal agencies, individual citizens, environmental and public interest groups, industry and trade associations, pesticide users, health professionals, academia, foreign governments and international organizations, Congress and other federal agencies, and the media.

Appropriate outreach activities are vital to OPP's efforts to ensure that groups and individuals have the information they need to make responsible decisions about pesticides and promote public health and environmental protection goals. The challenge is to make information widely available, easily accessible, and suited to the needs of OPP's many “publics.” To accomplish this, OPP issues announcements and publications for both general and scientific audiences, provides information by telephone and electronic network, responds to written requests for information, maintains a public docket for walk-in visitors, holds public meetings, and presents speeches and Congressional testimony. This section describes some of the ways OPP provides information and obtains valuable public input. Additional information on electronic information dissemination is found in chapter 6.

Outreach And Communications Strategies

In 1995, OPP issued approximately 65 announcements informing the public of major regulatory and policy decisions, continuing an upward trend from 1994. Each announcement is planned using a communications strategy, which often entails a press notice and additional outreach materials, such as fact sheets or questions and answers. In addition, OPP issued background materials to respond to inquiries arising out of media reports on pesticide-related issues.

Public demand for pesticides information increased dramatically in FY 1995. Directly and through the National Center for Environmental Publications and Information, OPP managed distribution of over 700,000 copies of publications, a four-fold increase over FY 1994.

OPP is working with others inside and outside EPA to increase public awareness of available information resources on pesticides and ensure the most cost-effective, timely distribution of educational materials. One key accomplishment in FY 1995 was the production of an updated catalogue of pesticide publications. The catalogue was distributed in “hard copy” in 1995; it will be posted electronically and updated annually in the future.

Significant new publications developed in FY 1995 include joint publication with the Occupational Safety and Health Administration of a *Guide to Heat Stress for Agricultural*

Workers and a major update and expansion of OPP's core consumer publication, *Citizen's Guide to Pest Control and Pesticide Safety*, to be printed and distributed in FY 1996.

Protecting children from pesticide poisoning continues to be an important focus of outreach efforts. In collaboration with the Poison Prevention Council and the Consumer Product Safety Commission, OPP participated in Poison Prevention Week and other activities, distributing thousands of copies of fact sheets to medical establishments and the general public. Fact sheet topics included child safety and using insect repellents safely (both in English and Spanish).

Responding To The Public

Freedom of Information Act (FOIA) Requests

OPP responds to technical or complicated requests for information from the public under the Freedom of Information Act (FOIA). OPP continues to receive the highest number of FOIA requests of any program within EPA, and in fiscal year 1995 received 1,537 requests and completed 1,235 responses. The majority of requestors receive all of the records requested, with the most common requests being for science reviews of registration data, administrative files for pesticide products, and reregistration information.

OPP Public Docket

OPP has established four dockets to house the regulatory notices, background documents, and public comments on OPP activities. These consist of the Federal Register, Special Review, Registration Standard, and Special Program Dockets. The docket now has the capability to accept the electronic submission of public comments. The most active docket action was the Triazines Special Review, which received over 87,000 public comments. Over 2,000 requests for docket information received by letter, telephone, and in person were filled in fiscal year 1995.

National Pesticides Telecommunications Network (NPTN)

NPTN is a national service accessible by a toll-free telephone number that provides objective information about pesticides upon request to anyone in the United States, Puerto Rico, and the Virgin Islands. The service operates Monday through Friday from 6:30 a.m. to 4:30 p.m. (Pacific Time). NPTN provided services to more than 17,000 callers during fiscal year 1995, including approximately 1,700 calls concerning pesticide incidents. The remaining calls were requests for general information on pesticide products and issues concerning health, safety, and use.

National Pesticide Medical Monitoring Program (NPMMP)

The NPMMP, located at Oregon State University, provides information and referrals on clinical toxicology questions and analytical services for biological and environmental samples. Health care professionals and possible victims of pesticide poisonings are major users of the service. NPMMP handled 452 incidents in FY 1995.

Other Letters and Inquiries

Rising public interest in pesticides and their effects on people and the environment is reflected in the hundreds of letters and telephone inquiries that OPP receives annually. In 1995, OPP prepared responses for senior EPA officials to over 1,600 letters, ranging from highly complex Congressional inquiries to postcard write-in campaigns. In addition to the docket letters described above, OPP received over 30,000 cards and letters supporting alternatives to animal testing and nearly 1,000 letters on biotechnology issues. The triazines Special Review (involving ground-water issues) was the next most popular topic, with over 70 letters. Other frequent subjects included the Worker Protection Standard, pesticides and children, the Delaney clause and other food safety issues. Over the past year, OPP laid the groundwork to be one of the first EPA offices to adopt a new automated correspondence control and information storage and retrieval system. This will enhance efficiency and allow improved responsiveness to OPP's many customers.

Congressional Relations And Coordination With Other Federal Agencies

Congressional interest and oversight of pesticide and food safety issues continues at a high level. Over 450 of the letters described above were responses to Congressional inquiries. In addition, OPP prepared testimony and briefing materials for four Congressional hearings on pesticide issues and activities, including implementation of the Worker Protection Standard and proposals for major changes in legislation governing pesticide regulation and food safety.

OPP continued to assist the General Accounting Office and EPA's Inspector General with several ongoing evaluations of pesticide program activities, including implementation of the Worker Protection Standard, activities to address alternatives to the pesticide methyl bromide (scheduled for phaseout under the Clean Air Act), management of the fees paid by pesticide registrants, incident monitoring and follow-up, the progress of reregistration of older pesticides, and a review of the effect of environmental laws and regulations on U.S. agriculture and other industry.

Pesticide and pest control issues often involve the jurisdiction of several federal agencies. To promote efficiency and consistency of federal effort, OPP coordinates many of its activities with those agencies through Memoranda of Understanding and less formal working groups. Some of the areas of common activity are: FDA — food safety and antimicrobial pesticides (such as hospital disinfectants); USDA — food safety and farm-related regulations (such as worker protection and pesticide storage and disposal); Consumer Product

Safety Commission — labeling issues; Department of Interior — endangered species; Occupational Safety and Health Administration — worker protection; Customs and Coast Guard — import and export issues; Department of Defense — pest control on military installations; and Department of Transportation — harmonization of safety standards for hazardous chemicals.

One example of OPP federal coordination in 1995 was its interagency agreement with the U.S. Geological Survey (USGS). This agreement will allow OPP to access USGS monitoring data and information on water quality trends, thereby enhancing OPP's ability to assess ground and surface water vulnerability to pesticide contamination and to make sound regulatory decisions to protect water resources.

National Agricultural Pesticide Impact Assessment Program (NAPIAP)

OPP played a significant role in the independent panel review of NAPIAP, a USDA program. Recognizing significant changes in the demands for information and in regulatory priorities, tight budgets, and government reinvention, the panel was charged with evaluating NAPIAP in the context of USDA's overall pesticide and pest management information function. The panel's report highlighted 13 key findings and recommendations. The report reaffirmed NAPIAP's primary mission to provide science-based benefits information that contributes to EPA's pesticide regulatory decisions. The report recommended improving benefits information by establishing formal procedures and assessment-specific protocols, and continuing to improve communications and cooperation between USDA and EPA. OPP is continuing to work with USDA to address these recommendations.

International Coordination And Integration

This section describes OPP's efforts to inform foreign governments about changes in the status of pesticides in the U.S. and major OPP programs. The purpose of these efforts is to help foreign governments, especially those that have not yet developed extensive pesticide regulatory and information-gathering programs, make informed choices about the use of pesticides in their countries. Not only do these efforts benefit citizens of foreign nations, but they also benefit Americans by helping to ensure the safety of imported food and other commodities treated with pesticides. In addition, these efforts help to protect wildlife, like migratory birds, that cross international borders.

Export Notification for Unregistered Pesticides

For all exports of pesticides not registered in the United States, section 17(a) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires the U.S. exporter to obtain a statement from the buyer acknowledging that the product is not registered. The exporter must submit this statement to OPP, and OPP forwards a copy to the importing government. In 1995, OPP transmitted approximately 2,000 export notifications for about 260 pesticide active ingredients to the governments of more than 125 importing countries. Since 1992, reporting has increased by more than 150% for exports containing active ingredients

approved in other U.S. products, but where the particular export formulation is not registered by OPP. In 1994, such pesticides comprised more than half of the unregistered pesticide exports.

Reinventing EPA's Pesticide Export Notification Program

In September 1995, as part of the effort to reinvent government, OPP made options for revising its pesticide export notification policies available for public comment. The key option would take a risk-based approach in determining when export notices would be required, significantly reducing the number of exports subject to notification. After consideration of comments, OPP will revise its current requirements. In addition, the European Union (EU) has recently announced plans to revise its pesticide export regulations. This announcement presents an opportunity for the United States to work with the EU in developing complementary export notification programs.

Information Exchange with Foreign Countries

Another provision of FIFRA, section 17(b), requires OPP to share information with health and environmental agencies in other countries. Under this requirement, OPP sends notices to other governments on important regulatory decisions made in the United States related to pesticides, food safety, and pest management. In 1995, OPP transmitted 31 notices covering a range of regulatory actions, such as initiation of the triazine Special Review and the new agricultural Worker Protection Standard. Notifications are distributed directly to pesticide regulatory authorities in approximately 140 countries.

Prior Informed Consent (PIC)

OPP continues to actively participate in this joint program developed by the United Nations Environment Programme (UNEP) and the U.N. Food and Agriculture Organization (FAO) to promote the safe management of chemicals in international trade. PIC establishes a mechanism whereby importing countries can receive information about pesticides and industrial chemicals and then make informed decisions on whether to allow, restrict, or prohibit future imports. In 1995, OPP prepared a discussion paper for FAO/UNEP on determining which pesticides pose particular concerns under conditions of use in developing countries, reviewed draft FAO/UNEP Decision Guidance Documents prepared to assist importing countries, and responded to requests from other countries for additional information.

Work progressed internationally toward making PIC a legally binding instrument. Formal negotiations toward an international treaty are expected in FY 1996.

International Visitors

OPP arranges briefings with key U.S. officials for foreign visitors interested in U.S. pesticide policies and scientific evaluation procedures. During the past fiscal year, OPP hosted 85 visitors, including representatives from Australia, Brazil, Canada, Chile, Denmark, France, Hong Kong, Indonesia, Japan, Latvia, Malaysia, South Korea, Moldova, New Zealand, Russia, Taiwan, the United Kingdom, and Venezuela.

Regional, State, And Tribal Liaison

Regional Coordination

EPA's 10 regional offices are OPP's primary connection to state, territorial, and tribal governments. They negotiate cooperative agreements for OPP's field programs, assist in developing and implementing programs, and oversee accomplishments and commitments made by the states, territories and tribes. Regional staff communicate OPP's programs and policies to the public and in turn provide OPP with public input.

State and Territorial Programs

States and territories are true partners with EPA in protecting human health and the environment from pesticide risks. They assist in developing and implementing field programs, and they enforce OPP's regulations and pesticide labeling and use requirements. To further these common goals, OPP supports a cooperative agreement with the Association of American Pesticide Control Officials for the State FIFRA Issues Research and Evaluation Group (SFIREG). In 1995, SFIREG continued to meet periodically with OPP to develop pesticide programs and discuss implementation and enforcement issues of concern to the states and territories.

Tribes

Native American tribal governments have sovereign rights and certain specific assurances from the federal government under treaties. The capacity of tribal governments to carry out environmental regulatory programs varies significantly from tribe to tribe, and the challenge for OPP is to accommodate tribal differences while ensuring that basic health and environmental protections are achieved for all Native Americans.

OPP is working with tribes to assist them in building capacity to conduct regulatory and field programs for pesticides. In 1995, OPP helped fund an environmental scholarship program to assist college students studying environmental sciences and interested in addressing Native American issues. OPP also sponsored a Native American intern to work on these issues and learn more about how EPA works, supported efforts by the Native American Higher Education Consortium to develop college-level courses related to pesticide safety,

and developed and piloted a seminar on Native American culture and history for OPP staff.

OPP is also addressing specific issues uniquely affecting Native Americans. In 1995, OPP continued work with other state and federal authorities to address potential pesticide exposure by members of the California Indian Basketweavers Association (CIBA). CIBA members are concerned about potential exposure to pesticides from contact with native plant materials used in traditional basketweaving.

Laboratory Tools

Pesticide Chemistry Laboratories (PCLs) in Beltsville, Maryland, and Bay St. Louis, Mississippi, support EPA regions and states with technical reference standards, technical assistance, and laboratory services. (Technical reference standards are pesticide samples of known concentration that can be used, for example, in verifying the formulations of pesticides being offered for sale.) In FY 1995, OPP distributed 735 technical reference standards to the regions and states, and PCLs responded to 76 requests for assistance. Most of the requests came from chemists in other federal, state or private labs. OPP's PCLs are the primary repository for all food tolerance, product, and environmental chemistry methods, as described in chapters 1 and 2.

In 1995, OPP also drafted an Environmental Chemistry Methods Manual describing how to detect pesticides in soil and water. When finalized, it will include introductory chapters, formatted methods developed by EPA or pesticide registrants, and technical appendices. OPP is planning wide distribution and will make the manual available to public and private labs for a fee.

Chapter 5: Policy, Regulations, and Guidelines

OPP makes many individual decisions in its registration, reregistration, and special review programs. To guide these decisions and inform its many stakeholders, OPP develops regulations, policy documents, guidelines and analyses covering scientific, legal, and international matters. Active public participation and feedback is critical to the development of practical pesticide policies. Regulations are published for notice and comment in the *Federal Register*. When final, they are incorporated in the *Code of Federal Regulations*. OPP makes other policy and guidance documents available through a variety of mechanisms, such as the Government Printing Office, direct mailings, and increasingly, through electronic dissemination. This chapter highlights some key areas of progress over the last fiscal year.

Improving Protection For Infants And Children

OPP has made substantial progress implementing recommendations in the 1993 report of the National Academy of Sciences (NAS), *Pesticides in the Diets of Infants and Children*. The report made recommendations to improve protection of infants and children in four areas: toxicology, risk assessment, residue chemistry, and food consumption.

Toxicology

- ▶ To better assess newborn and pre-adolescent toxicity, EPA's Scientific Advisory Panel (SAP) peer reviewed in 1995 a number of data requirements developed by OPP. The requirements are for assessing the potential effects of pesticides on immune function, the nervous system, reproduction and development, and the visual system. The requirements will be proposed in 1996 as part of comprehensive revisions to OPP's data requirement regulations (40 CFR Part 158).
- ▶ Test guidelines for each of these areas have been developed (neurodevelopmental, neurotoxicity) or will be completed in 1996 (reproductive/developmental, visual system).
- ▶ The National Toxicology Program at the Department of Health and Human Services (HHS) completed a pilot study on the use of an additional thyroid test which is now being evaluated by OPP.

Risk Assessment

- ▶ EPA is revising its guidelines for assessing the cancer risks posed by chemicals to take into account all available biologically-based information.
- ▶ OPP is phasing in the evaluation of multiple routes of pesticide exposure (such as from food, drinking water, and household use) and combined exposures to multiple pesticides which have the same mechanism of action (that is, they cause the same toxic effect in the same way). For example, in the Special Review of the triazine family of

pesticides, the potential combined risks from consumption of these chemicals in food and drinking water is being considered along with application exposure via agricultural and residential use. In addition, OPP now routinely addresses the potential for additive risks from drinking water and food in making reregistration decisions. Evaluation of exposure to children and other potentially sensitive subpopulations is a routine aspect of dietary risk assessments in both the registration and reregistration programs.

Food Consumption

- ▶ To provide more reliable information regarding exposure to pesticides in foods, OPP will be using USDA's Food Grouping System in standardizing the "recipes" used to convert foods "as eaten" (for example, pizza) to raw agricultural commodities (for example, wheat, and tomatoes). In addition, OPP is revising its commodity list which, upon completion, will be transmitted to USDA so all recipes can be standardized based on the new commodity list by the end of 1996.
- ▶ USDA requested additional funds to carry out a supplemental food consumption survey, but monies were not appropriated. OPP is working with USDA and HHS, as part of the Food Consumption Working Group, to design future surveys.

Residue Chemistry

- ▶ A design for a National Pesticide Residue Monitoring Database is complete and could be implemented in FY 1997, if funds were available.
- ▶ OPP completed a market basket feasibility study for monitoring pesticides in the top 20 foods eaten by children.
- ▶ OPP routinely uses actual field trial data to estimate potential residues in treated food. Guidance specifying number of field trials per crop was peer reviewed by the SAP and completed in 1995.

Acute Dietary Risk Assessment Policies

Acutely toxic pesticides are those which could cause illness or injury based on short term exposure to excessive residues. For example, high residues of such a pesticide in food could cause illness to some people after a single serving of the food. Unlike potential chronic effects, which are evaluated based on likely consumption of foods containing varied residue levels over many years, acute effects must be evaluated based on the possibility of excessive exposure to "high residue" foods within a relatively short period. Using average residue values in evaluating health risks would not provide an adequate margin of safety for consumers in the case of acutely toxic pesticides.

In FY 1995, OPP developed new, refined guidance for determining potential risks posed by acutely toxic pesticide residues in food. The policy optimizes the use of available residue data and takes a tiered approach, proceeding from worst case assumptions to more realistic assumptions. The new approach incorporates recommendations from the National Academy of Sciences report on *Pesticides in the Diets of Infants and Children* and was presented to the OPP's Science Advisory Panel for expert peer review in October 1994. The new policy standardizes OPP risk assessment for acutely toxic pesticides, enabling the agency to compare risks more directly and to make sound, protective tolerance decisions.

Activities Related To Implementation Of The “Delaney Clause”

Following a 1992 decision by the Ninth Circuit Court of Appeals, OPP has made progress implementing the Delaney clause of the Federal Food, Drug and Cosmetic Act (FFDCA). The Delaney clause prohibits the establishment of food additive regulations or maximum residue limits for *processed* foods for any pesticide that induces cancer in humans or test animals. In FY 1995, EPA:

- ▶ Proposed in January to revoke six food additive regulations involving four pesticides found to induce cancer, continuing the orderly process of making decisions on existing food additive regulations potentially subject to the Delaney clause initiated in July, 1994.
- ▶ Obtained a court approval in February of a settlement with the Natural Resources Defense Council and others (NRDC settlement) to take a number of actions within certain time frames to comply with the Delaney clause as interpreted in the Ninth Circuit decision.
- ▶ Articulated commonsense, science-based policies for defining when pesticide residues concentrate in processed food and when processed food is considered “ready to eat.” These new policies, published in June, responded to certain issues raised by the National Food Processors Association and others. Although established as a result of Delaney actions, the policies apply to the tolerance setting process in general. A significant consequence of these policies is that fewer food/feed additive tolerances will be needed for processed foods, due to more realistic assumptions of the likelihood of residues in processed foods.
- ▶ Began applying these new policies in a number of specific tolerance decisions. For example, in August, EPA proposed to revoke tolerances for trifluralin in mint oils since mint oils are not “ready to eat,” and residues in ready-to-eat foods made with mint oils would not be higher than the raw agricultural commodity tolerances. In September, the Agency proposed the revocation of 36 livestock feed additive regulations involving 16 pesticides. Of these, 34 proposed revocations were based on a determination that they were no longer needed (e.g., the residues were found not to concentrate in ready-to-eat processed feed), while two revocations were proposed because the tolerances violate the Delaney clause. With this action, EPA completed

initial proposals on all existing food additive regulations that had been identified as potentially subject to Delaney. Final decisions will be made on these proposals between December 1995 and March 1997.

Revised Food And Livestock Feed Table

OPP has issued a revised version of its Food and Livestock Feed Table (Table 2 of Subdivision O of the Pesticide Assessment Guidelines, entitled "Raw Agricultural and Processed Commodities and Feedstuffs Derived from Field Crops"). This table lists raw and processed human foods and livestock feeds (derived from field crops) for which tolerances are established and residue data are required.

Changes to the table were needed to reflect significant changes in livestock feeding practices in recent years. Some commodities formerly listed (such as barley bran and tomato paste) are no longer considered to be significant feed items and have been dropped from the table. Residue data and tolerances are no longer required for these commodities. This new information on feeding practices improves the accuracy of exposure assessments for residues in livestock-derived foods. OPP has already begun using the new table in making tolerance decisions.

"Reinvention" and Regulatory Reform: Ongoing Efforts to Clarify and Update Regulatory Policies and Requirements

FY 1995 was a year of significant progress in a number of ongoing efforts to update and reform core OPP policies in order to improve the quality of pesticide regulatory decision-making and make OPP's requirements clearer and more consistent.

Comprehensive Review of Existing Regulatory Burdens

In the spring of 1995, President Clinton directed all federal agencies to reduce regulatory burdens and signed into law a new Paperwork Reduction Act. In response to the President's call, OPP mounted a concentrated effort to review every regulation on the books, with the goals of eliminating outdated or unnecessary rules and reducing reporting and recordkeeping requirements where appropriate. All interested stakeholders had the opportunity to become involved in this effort, through public meetings and solicitation of written comments.

OPP reported back to the President in June, 1995, and announced a number of new initiatives designed to streamline and reduce burdens posed by pesticide regulation. Highlights included steps to exempt low-risk pesticides from regulation, eliminate regulatory overlap between EPA and the Food and Drug Administration for certain products, and permit minor changes in the conditions of pesticide product registrations without prior OPP approval. OPP is also exploring other approaches to reducing regulatory burdens, including implementation of self-certification programs for certain registration requirements. Finally, as described in

more detail in chapter 4, OPP is reviewing current policies with a view toward “reinventing” its export notification programs.

Tolerances and Food Safety

In FY 1995, OPP continued to work on proposals for reinventing its processes for establishing tolerances and estimating risks to consumers (including children) from exposure to pesticide residues in food.

A major component of this effort was the opening up of OPP's current procedures for wider public review and comment. Based on the comments received, OPP has already taken steps to incorporate improved statistical techniques into dietary exposure analyses and to consider average field trial residues in determining the need for separate tolerances for processed foods.

OPP is continuing to assess the comments received and expects to announce a number of additional changes in FY 1996. Some of the changes under consideration are designed to take into account factors known to reduce pesticide residues in foods between the time crops are harvested and eaten (e.g., washing and peeling) when setting tolerances. Other proposals involve gathering more data on pesticide usage and actual residues on crops in order to make more accurate estimates of dietary exposure, harmonizing terminology with current international practices, improving OPP's ability to track total dietary exposure for food use pesticides, and developing materials to improve public understanding of the tolerance-setting process. The goal is to establish tolerances that more closely reflect real exposure to residues in food and to make the tolerance-setting process more open and accessible to the public.

Revised Pesticide Registration Data Requirements (40 CFR Part 158)

As part of the Administration's regulatory reform initiative, OPP has undertaken a comprehensive review and updating of its pesticide data requirements, found in Title 40 Part 158 of the *Code of Federal Regulations*.

In 1995, OPP submitted a draft proposal to the Scientific Advisory Panel (SAP) for peer review. Among other provisions, the proposal includes significant regulatory relief for biological pesticides, sets forth data requirements for clearance of inert ingredients of pesticides, and provides more explicit criteria for when specific types of studies are required for agricultural uses of pesticide chemicals. For the most part, the SAP endorsed the proposed changes, except for a provision to require comparative performance testing. Based on the SAP response, OPP plans to issue a proposed rule for full public comment in 1996.

In addition, OPP made significant advances in laying the groundwork for revising data requirements for biocides and other non-agricultural pesticides and tailoring them to reflect specific use and exposure conditions. Collaboration with Canada and the European Union to promote international harmonization of data requirements and testing strategies for non-agricultural pesticides also began during this fiscal year.

Draft Guideline for Independent Laboratory Validation of Environmental Chemistry Methods

OPP published a draft data reporting guideline that requires registrants to obtain independent laboratory validation of methods used to detect pesticide residues in soil and water. The guideline applies to nine environmental fate, exposure and ecological effects studies that OPP requires of pesticide registrants. The guideline is based on OPP's findings that a large number of existing detection methods were incomplete, inadequately documented and insufficiently effective, while other methods used outdated technology no longer available in EPA laboratories. These new guidelines will save OPP resources and reduce delays in reviewing methods. A revised draft is planned to be published in the *Federal Register* in early 1996.

Guideline Harmonization and Updating

In another regulatory reform initiative, OPP is nearing completion of a multi-year project to harmonize its pesticide chemical test guidelines with those of the EPA's Office of Pollution Prevention and Toxics, California, and the Organization for Economic Cooperation and Development (OECD), an international organization that includes most major industrialized countries among its members.

OPP's test guidelines outline how studies should be designed and conducted in order to satisfy OPP's regulatory requirements and support pesticide registration. Greater clarity and consistency in test requirements will eliminate duplicative or redundant testing and provide greater assurance that pesticide studies reflect the best, most current science. As harmonization and updating efforts are completed, the test guidelines are being consolidated into a single cataloguing system and will be made available through the Government Printing Office beginning in 1996.

EPA currently has 340 guidelines, organized into 10 categories based on scientific discipline. Once the Agency has reviewed a guideline and developed an updated/harmonized version, the revised guideline is subject to peer review and international notification where appropriate, prior to publication.

Accomplishments in FY 1995 included:

- ▶ Guidelines harmonized and/or updated
 - Toxicology (57)
 - Nontarget Organisms (45)
 - Residue Chemistry (18)
 - Physical Chemistry (25)
- ▶ Guidelines Peer Reviewed
 - Residue Chemistry (18)
 - Physical Chemistry (25)

- ▶ Guidelines Ready for Republication
 - Applicator Exposure (7)
 - Post Application Exposure (9)
 - Microbial Pest Control Agents (44)
 - Biochemical Pest Control Agents (7)

OPP plans to publish all remaining test guidelines after appropriate peer review and public comment during 1996.

Methyl Bromide Alternatives

Methyl bromide is a broad spectrum pesticide which is effective in controlling insects, fungi, nematodes, and weeds when used to fumigate soil, structures, and commodities. However, it has also been found to contribute to depletion of the ozone layer. Consequently, under the Clean Air Act, EPA has prohibited the production and importation of methyl bromide after January 1, 2001. In light of this phaseout, EPA is cooperating with the U.S. Department of Agriculture, commodity groups, and others to give priority to the development, registration, and adoption of alternatives to methyl bromide, including both chemical and non-chemical pest control strategies.

In 1995, OPP issued two formal policy statements: a commitment to giving priority review to methyl bromide alternatives, and a requirement that applications for “emergency exemptions” involving methyl bromide use demonstrate efforts to develop alternative means of pest control. In keeping with its overall policy of reducing pesticide use and risk, OPP also supported the Port of San Diego's efforts to develop an innovative technology to capture and reuse methyl bromide in its quarantine fumigation operation. This method has the potential to decrease use and emissions of methyl bromide.

Other Ongoing Regulatory Improvement Initiatives

OPP made significant progress on a number of additional regulatory improvement initiatives during 1995, including work toward publication of several key proposed and final rules:

- ▶ **Final rule clarifying responsibilities for reporting pesticide incidents (“6(a)(2) Rule”).** Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act requires registrants to report incidents and other information indicating potential adverse effects of pesticides. This information is important in helping OPP decide if action should be taken to reduce the risks posed by a particular pesticide. In 1995, OPP completed a draft final rule to clarify the reporting obligations. OPP expects to publish the final rule in early 1996. (Chapter 6 provides further discussion of 6(a)(2) activities during 1995.)
- ▶ **Ground-water protection regulations.** Complementing the ongoing field activities described in chapter 4, OPP also continued regulations development to protect ground water. Progress in 1995 included drafting a final rule defining criteria for identifying

pesticides posing risks of ground-water contamination and a proposed rule to require state management plans for several specific pesticides that are frequently detected in ground water.

- ▶ **Standards for pesticide containers and containment.** Approximately 200 comments, totalling 2900 pages, have been received in response to OPP's February 1994 proposed regulation establishing standards for pesticide containers and containment. In 1995, OPP reviewed, abstracted and summarized these extensive comments, in preparation for the development of a final rule.

Ecological Risk Assessment and Ground-Water Study Guidance

In FY 1995, OPP launched an initiative to standardize and improve ecological risk assessments by creating a source of clear, easily accessible, up-to-date guidance documents for ecological reviews. The effort involved an extensive compilation and review of existing documents, updating established guidance, writing new guidance, and providing for internal peer review by senior scientists. The highest priority documents should be complete by December, 1995.

OPP scientists also developed draft guidance on a new design for small-scale, prospective ground-water monitoring studies. These studies are used to determine if residues may leach into ground water and often serve as the basis for restrictions on pesticide use to prevent ground-water contamination. The draft guidance drew hundreds of comments, most supporting OPP's proposed changes and many expressing appreciation for the opportunity to provide input at an early stage of policy development. OPP plans to issue final guidance in FY 1996.

Community-Based Environmental Protection

As part of the EPA-wide effort to promote community-based environmental protection initiatives, OPP participated in the development of a strategy for the Office of Prevention, Pesticides, and Toxic Substances that stressed providing information tools and creating partnerships for community-based ecosystem protection projects. In 1995, OPP launched its own Ecosystem Pilot Project, which included the following activities:

- ▶ Participating in a joint federal-state assessment of environmental conditions in the Southern Appalachian Region. OPP provided information on pesticides in ground water and data from its Ecological Incident Information System.
- ▶ Undertaking a survey to identify and catalogue the knowledge and expertise available from OPP to assist in ecosystem protection initiatives.
- ▶ Working with EPA's Office of Water to train teachers in such areas of environmental concern as pollution prevention and preservation of streams. The program is intended

to develop partnerships with minority colleges, beginning with a pilot in Petersburg, Virginia.

Improving Methods, Modeling, And Information Systems for Environmental Assessments

OPP scientists and statisticians continued to make progress in a number of areas aimed at improving methods and information systems that support pesticide decision-making. Accomplishments in 1995 included:

Mapping, Monitoring, and Modeling Pesticides in the Environment

Desktop Geographic Information System (GIS) mapping is now being used on a regular basis in OPP. New software integrates the visualization of geographic data with traditional tools like spreadsheets, databases, and business graphics. In FY 1995, OPP used desktop GIS to map pesticide use areas and pesticide detections in ground water. Integration of mapping with OPP's Ecological Incident Information System enables the system to combine visual displays showing location of pesticide contamination incidents with information on county and state boundaries, major roads, rivers, cities and land use patterns.

OPP also continued to participate in collaborative efforts to improve monitoring and modeling of pesticides in the environment. For example, OPP contributed to the work of the Intergovernmental Task Force on Monitoring Water Quality to improve coordination of monitoring efforts and make the data more useful and widely accessible nationwide. OPP also participated in the Exposure Modeling Workgroup, a partnership that includes the U.S. Department of Agriculture and private sector experts. The workgroup is developing improved computer models of how pesticides break down and are transported in the environment. 1995 accomplishments included finalizing guidance on how to select the values, such as soil type and climate, to input to models and how industry should report results to OPP. The partnership also made substantial progress in standardizing the types of locations that should be modeled for each major crop and in determining the accuracy of modeling.

Statistical and Computer Program Improvements

OPP statisticians and scientists work continually to improve the efficiency and consistency of ecological effects data evaluations. The goal is to enhance confidence that conclusions are based on appropriate procedures, which enable OPP to better characterize the environmental risks of pesticides and evaluate reductions in risk resulting from regulatory decisions. To further these objectives in 1995, OPP conducted an in-house workshop and participated in conferences on ranking environmental risks and measuring uncertainty in ecological risk assessment.

In 1995, OPP also worked to design an “environmental fate tool box,” a series of computer programs that will help OPP understand how fast pesticides break down in the environment and the degree to which they can move through soil into ground water.

Legislative Proposals

EPA worked with the Department of Agriculture, the Food and Drug Administration, and others in the executive branch to develop Administration positions on proposed legislation relating to pesticides and food safety, prepare for Congressional hearings on these topics, and communicate the Administration's positions to members of Congress, their staffs, and the public. OPP provided analyses of antimicrobial reform legislation and a variety of funding options for reregistration and registration. In addition, OPP led a number of educational briefings for members and staff on key pesticide issues.

The Administration is committed to working with Congress to enact sound reforms to both major pesticide statutes, the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). In particular, Administration goals include adopting a single, health-based standard for pesticide residues in food; ensuring implementation of recommendations contained in the National Academy of Sciences report *Pesticides in the Diets of Infants and Children*; promoting the development of reduced risk pesticides; providing incentives for registering minor use pesticides; and providing OPP with the fee revenue required to complete on-going reregistration reviews, as mandated by Congress in 1988 amendments to FIFRA.

While no bills were introduced in 1995 that fully addressed all of EPA's concerns, OPP is continuing to work with Congress toward the goal of enacting legislation that will provide a strong, consistent framework for its efforts to better protect public health and the environment.

International Harmonization And Regulatory Coordination

OPP's international harmonization projects aim to develop common or compatible international approaches to pesticide review, registration and standard-setting. Common approaches to regulation will allow work sharing and reduce regulatory burdens on national governments, improve the science supporting pesticide regulatory decisions worldwide, provide greater assurance that imported food is safe, and reduce trade problems and costs for registrants.

OECD Pesticide Forum

The Pesticide Forum of the Organization for Economic Cooperation and Development (OECD) brings pesticide regulators together to address common problems, promote harmonization of policies and procedures, and enable work sharing. The U.S. participates in a number of ongoing Forum projects, including: (1) providing feedback to the European Commission on Europe's new registration/reregistration procedures; (2) working with

Australia and Canada on guidance for interpreting studies and documenting data reviews for subchronic oral toxicity (90-day rodent) tests; (3) developing common test guidelines; (4) exchanging data reviews; and (5) participating in a survey and a workshop on pesticide risk reduction activities. As a result of Forum activities, countries are developing much closer working relationships and are beginning to share information on a more routine basis. Specific examples in 1995 include:

- o Cooperation among the U.S., Germany, and Canada to use Canadian reviews and new registrant data to facilitate review and establishment of a U.S. tolerance for amitraz on hops.
- o Cooperation between the U.S. and Australia to resolve problems of chlorfluazuron residues in imported beef.

Intergovernmental Forum on Chemical Safety

In response to the Agenda 21 Report prepared at the 1992 United Nations Conference on Environment and Development, U.N. member countries established the Intergovernmental Forum on Chemical Safety (IFCS). The IFCS coordinates national and international chemical safety activities in a number of areas: (1) risk assessment; (2) harmonization of classification and labeling systems; (3) information exchange, including prior informed consent (PIC); (4) risk reduction; and (5) strengthening national capabilities. The IFCS is improving global coordination of chemical safety activities, including high visibility initiatives such as PIC and Persistent Organic Pollutants, which are described separately in this report.

In support of the goals of Agenda 21, OPP contributed to the design of a model risk assessment document and prototype production process. The resulting documents, known as Concise International Chemical Assessment Documents (CICADs), will provide internationally peer reviewed risk assessments for priority chemicals. OPP also drafted a CICAD for the pesticide amitraz.

During FY 1995, OPP helped plan and participated in a meeting of 14 American countries that are members of the IFCS to establish regional priorities for chemical safety. This expanded Americas meeting, chaired by Mexico, established good working relationships among the countries represented and provided a foundation for greater chemical safety in the Americas.

Canada/U.S. Technical Working Group on Pesticides

The Canada-U.S. Trade Agreement (CUSTA) directed the two countries to work toward equivalence of pesticide standards. The more recent adoption of the North American Free Trade Agreement (NAFTA) by Canada, Mexico, and the United States emphasized the goals of harmonization, without lowering the level of public health and environmental protection in any country, and cooperation to enhance conditions throughout the hemisphere.

To further these objectives, CUSTA established a Technical Working Group (TWG) on Pesticides. This group is currently co-chaired by OPP and the Pest Management Regulatory Agency of Canada. In light of NAFTA, Mexican regulatory authorities have also been invited to participate, and attended the first trilateral meeting in 1995.

After initiating various pilot projects to become knowledgeable about and confident in each country's regulatory processes, in 1995 the TWG began moving toward more active harmonization and actual work-sharing. For example, OPP utilized Canadian reviews of acute toxicity data in registering a product, thereby saving significant review time. OPP will also use Canadian reviews in the reregistration process for creosote, an important wood preservative.

In addition, the TWG has made significant progress in cooperation with agricultural producers and industry to reduce trade disruptions caused by differences in residue limits between the U.S. and Canada. In 1995, equivalent import tolerances were established for six pesticide/crop combinations (permethrin on spinach; acephate on beans, peppers, and cranberries; clethodim on potatoes; and dimethoate on blueberries), eliminating trade barriers for affected commodities. Moreover, the U.S. registered the new, reduced-risk pesticide tebufenozide after conducting a collaborative review with Canada. The two countries also began to share information in the areas of occupational exposure, toxicology, and environmental effects and initiated scientific staff exchanges. A more complete description of the TWG's achievements can be found in its first formal Accomplishments Report, issued in June 1995.

Persistent Organic Pollutants (POPs)

A number of chemicals, known as persistent organic pollutants (POPs), present health and environmental risks due to their persistence in the environment, toxicity, tendency to bioaccumulate, and potential for long range transport. POPs have become an issue of global concern as they have been detected throughout the world, including remote Antarctic and Arctic regions. Although EPA has banned most pesticides considered to be POPs, such as aldrin, DDT, and dieldrin, they continue to be used in other countries, and residues persist in the United States.

OPP is currently working with other EPA offices and U.S. agencies to develop mechanisms to address POPs at the global level. In FY 1995, OPP contributed information on the health and environmental effects of POPs and provided guidance on criteria for identifying POPs of greatest concern to such international agencies as the U.N. Environment Programme and the U.N. Economic Commission for Europe/Convention on Long Range Transboundary Air Pollution. OPP is also assisting in the development of strategies for reducing the use of POPs in this hemisphere through the North American Commission for Environmental Cooperation.

Technical Cooperation With Developing Countries

As a world leader in pesticide regulation and environmental protection, EPA is often called upon to work with developing countries to improve pesticide safety. Requests range from responses to specific inquiries to longer term projects aimed at building institutional capacity. Following are highlights of several initiatives managed by OPP in FY 1995.

AID/EPA Central American Project

According to the World Health Organization, Central America has the highest per capita pesticide use in the world. The impact on human health and the environment is significant. Since 1992, the U.S. Agency for International Development (AID) and EPA have been implementing a model collaborative program designed to enhance Central American efforts aimed at improving appropriate pesticide regulation and use, and achieving food safety, public health, and environmental protection goals.

In 1995, one of the project's major accomplishments was the effort to upgrade regional pesticide laboratories in Central America. OPP and FDA jointly surveyed pesticide laboratory needs and capabilities, developed regional workshops for laboratory personnel, and produced the first-ever comprehensive laboratory training course and manual. Participants from five Central American countries attended a comprehensive training course sponsored in cooperation with FDA in June 1995. This “train the trainers” technical cooperation should enhance pesticide regulation and control throughout the region.

In 1995, the EPA-AID Central American project also completed the Spanish translation of two important reference documents: 1) *Regulatory Guide for Exporters of Nontraditional Crops from Latin American and the Caribbean Countries*, an overview of the roles and regulations of U.S. federal agencies affecting the import of fresh fruits and vegetables; and 2) *Recognition and Management of Pesticide Poisonings*, a valuable tool for the early diagnosis and treatment of acute poisonings.

Overall, the EPA-AID Central American project has formed an “essential alliance” that facilitates free information flow and appropriate technical assistance, helps ensure the safe importation of agricultural products into the United States, and allows Central Americans to make informed decisions as they strive to improve their economies, sustain their natural resource base, and understand the importance of environmental protection. One measure of the success of the pilot project, which was to conclude at the end of FY 1995, is that it has instead been expanded to cover broader environmental issues.

Indonesia

In FY 1995, EPA launched a two-year cooperative project to assist Indonesia's Ministry of Agriculture in improving pesticide regulation. EPA's involvement is a part of two larger projects, a pesticide management project funded by a five-year World Bank loan and an agribusiness project funded by AID. OPP will furnish data on pesticides that the Indonesian

Ministry will access via Internet. OPP and other EPA staff are also working with Agriculture Ministry staff to evaluate information needs and develop solutions to specific issues including regulation of pesticides of particular concern, enforcement, legislative reform, and pesticide storage and disposal.

Accomplishments in 1995 include:

- ▶ Preparing an assessment of acute risks to workers for 10 of the 16 pesticides identified as posing particular concerns under conditions of use in Indonesia.
- ▶ Providing pesticide-specific information to assist in Indonesia's evaluation of certain pesticide risks.
- ▶ Summarizing non-EPA sources of pesticide information on the Internet to assist Indonesia's use of this resource and to avoid duplicating information that is already available.

Pesticide Disposal

OPP worked closely in FY 1995 with the U.N. Food and Agricultural Organization (FAO), the U.N. Environment Programme, and the World Health Organization to issue two new technical guidance documents to assist developing countries in disposing of both large and small quantities of pesticides. In addition, OPP is working with FAO and other organizations to resolve the growing problem of massive quantities of obsolete pesticides requiring disposal.

International Fund For Agricultural Development

An OPP staff member is on assignment to the International Fund for Agricultural Development (IFAD) in Rome to address social and environmental impacts which may result from use of agricultural inputs, including pesticides, in the Fund's projects. IFAD is a specialized United Nations agency devoted to alleviating rural poverty. In 1995, OPP helped prepare an Operational Statement on Pesticides to assist IFAD project design and helped prepare for a 1996 international workshop entitled *Pest Management Approaches Suitable for Small-Scale Farmers*. These efforts are aimed at reducing hunger and poverty, while providing farmers with sustainable and cost-effective crop protection capabilities. Besides helping local farmers, such efforts should benefit U.S. citizens through safer imported foods, a healthier environment, and stronger and more stable economies in developing countries.

International Trade and Environment Policy

With the approval of the NAFTA and the new World Trade Organization (WTO) agreements, OPP has been called upon increasingly in recent years to support trade policy initiatives and implement efforts promoting international environmental goals and regulatory coordination.

Notably, in 1995 OPP served on delegations to the NAFTA and WTO Sanitary and Phytosanitary Committees, as well as a new working group for a Free Trade Agreement for the Americas. OPP also participated in preparatory discussions for the accession of Chile to NAFTA. OPP's goal in these deliberations is to promote international harmonization while safeguarding the integrity of the U.S. public health and environmental regulatory system.

In 1995, OPP continued to participate in the international food safety standard-setting activities of the Codex Alimentarius Commission. In collaboration with USDA and FDA, EPA took steps to enhance the scientific basis of Codex actions and increase public input into U.S. positions at Commission meetings. OPP also studied the steps needed to ensure compliance with U.S. obligations under international trade treaties to notify other countries of U.S. actions and consider international standards in making regulatory decisions.

Finally, as discussed in more detail earlier in this chapter, OPP supported EPA's Office of Air and Radiation and USDA in efforts to foster the development of alternatives to the ozone-depleting pesticide methyl bromide. In addition to U.S. laws, methyl bromide is subject to international controls under the Montreal Protocol, an international agreement governing ozone-depleting chemicals.

Chapter 6: Information and Program Management

OPP's information and program management activities are not as publicly visible as some of its other programs. However, these support activities keep the OPP engine running. The buildings OPP occupies; the supplies and equipment used; the careful planning, budgeting and administration of resources; the systems developed and maintained to process and store vast amounts of pesticide information — these are but a few examples of the critical program support efforts managed under this program area. Major achievements during 1995 are described below.

Operations, Maintenance And Integration Of The Primary OPP Information Systems

OPP has embarked on an effort to integrate virtually all of its many information systems under a single umbrella. These systems are used to track the hundreds of pesticides registered by OPP and the tens of thousands of studies associated with these pesticides. The systems include information about approved uses, reregistration status, product ingredients, and many other facts. Under the new Automated Information Management Master Implementation Plan, OPP is analyzing needs, linkages, and problems among the various systems. The analyses conducted in 1995 are expected to help achieve the goal of a unified system that provides consistent, comprehensive, and accurate information to all OPP users and that avoids multiple entries of the same data into different databases.

As work proceeded in planning for an umbrella data system, OPP made a series of improvements to existing information management systems. For example, the Pesticide Regulatory Action Tracking Systems (PRATS), which is used for tracking registration and reregistration actions, was enhanced to provide statistics on work accomplished every month by various OPP organizational units. The Chemical Review Management System (CRMS), which tracks reregistration information, was modified to track information for new pesticides. An innovative decision support system was developed to accept a wide range of toxicological (and other) data and generate a facsimile pesticide label containing the appropriate health and environmental warning language.

Finally, the OPP Local Area Network (LAN) Group upgraded the LAN infrastructure with new network technology resulting in an increase in network reliability. Remote access to OPP's LAN increased dramatically during 1995, with access extended to many EPA regional and headquarters employees. The group also established "One-Stop" Shopping to reduce the time it takes to create various network accounts, and increased the use of software employed in developing and executing surveys.

Electronic Dissemination Of Information

OPP continues to experiment with innovative ways of making information available to affected organizations and the general public. In 1995, OPP completed the process of enabling all OPP personnel to easily communicate with anyone on the worldwide Internet. OPP has also begun to make many of its publications and databases available on the Internet, and is developing plans to significantly expand the amount of OPP pesticide information that the public can access electronically. In 1996, OPP will request public comments on its plans to make additional information available electronically.

OPP currently uses three systems for delivering electronic access to its information: the EPA Internet servers, and two bulletin board systems, the Pesticide Information Network (PIN) and the Pesticide Special Review and Reregistration Information System (PSRRIS). OPP plans to consolidate its electronic information into a single system during the next fiscal year, so that users will find OPP's information at a single site. OPP will still offer both Internet and dial-up access. (For details on how to access the Internet site and bulletin boards, see the section entitled "How to Obtain More Information.")

Information Currently Available from OPP through the Internet

Almost all of OPP's electronically-available documents are available through the Internet, including all *Federal Register* notices and press announcements, and many Reregistration Eligibility Decisions (REDs). This information may be accessed using any of several methods in widespread use: through EPA's World Wide Web, Gopher, or FTP (file transfer protocol) servers. Interactive databases maintained on the PIN cannot now be accessed via Internet, but hardware and software changes planned for the coming year will provide single-point Internet access to all of OPP's electronically available information.

Pesticide Information Network (PIN)

The Pesticide Information Network (PIN) is a computerized, on-line collection of files containing current and historic pesticide information. This system is designed to enhance OPP's data gathering efforts; aid state agencies and others in obtaining needed information on a timely basis, thereby improving their ability to respond to local pesticide situations and federal requirements; save OPP resources through automated dissemination and updating of public information; and enhance cooperative efforts between EPA and other federal agencies through a convenient method of information sharing.

The PIN contains several different types of information. These consist of the Pesticide Monitoring Inventory (PMI) (including the Pesticides in Ground Water Database), the Ecological Incident Information System (EIIS) (described in more detail elsewhere in this chapter), a Regulatory Status database, the Certification and Training Bibliography, and a Biological Pesticides data set.

Pesticide Special Review and Reregistration Information System (PSRRIS)

This bulletin board system, or BBS, contains recent Reregistration Eligibility Decision (RED) documents and all the RED fact sheets. Other files available for downloading include basic information explaining reregistration and Special Review, lists of pesticides under review and the appropriate Chemical Review Managers' names and telephone numbers, the *Status of Pesticides in Reregistration and Special Review* (or Rainbow Report), *OPP Selected Terms and Acronyms*, OPP's Annual Reports, the Rejection Rate Analysis chapters, and the periodic *Pesticide Reregistration Progress Reports*.

Outside Sources of Electronic Pesticide Information

OPP plans to make use of, rather than duplicate, other sources of electronic information on pesticides. Internet users who access OPP's site will find reference and in some cases electronic links to other key pesticide databases around the world. For example, considerable information that is useful to the general public will soon be available through an Internet site being established by the National Pesticide Telecommunications Network (NPTN). NPTN currently offers a toll-free pesticide information hotline by telephone (1-800-585-PEST), a service operated by Oregon State University and partially funded by OPP. Another pesticide information resource with which EPA and OPP will link is the Global Information Network on Chemicals (GINC), an Internet-based project that has its roots in the June, 1992 U.N. Conference on Environment and Development (UNCED). This fledgling network intends to "promote intensified exchange of information on chemical safety, use and emissions" among all nations.

Other Information Systems

The Label Use Information System (LUIS). LUIS is a database of label directions that appear on pesticide products. It contains detailed information on approved use sites, application methods, application rates, and limitations on the use of pesticides (e.g., preharvest intervals, reentry intervals). LUIS can produce reports by active ingredient to support chemical regulatory decisions; it can also produce reports by product to monitor product compliance with regulatory decisions. In addition, the database can be used to help locate labels which match a specified parameter. In 1995, LUIS was used to support completion of Reregistration Eligibility Decisions (REDs), and the updating of records in LUIS focused on pesticides scheduled for reregistration. Work is also progressing to integrate LUIS with related databases and to make this data available electronically to all OPP staff.

Ecological Effects Pesticide Toxicity Database. OPP continues efforts to develop a database that will provide more comprehensive ecotoxicity data for registered pesticides used in the U.S. Over 410 active ingredients are presently covered by the database, which contains entries for over 9,100 studies on pesticide effects on terrestrial and aquatic plants, aquatic invertebrates, insects, amphibians, fish, birds, reptiles, and mammals. OPP receives approximately 20 database information requests per month from agricultural associations, private consulting firms, and international, federal and state agencies.

Pesticide Handler Exposure DataBase (PHED). In March 1995, OPP released a revised version of the PHED database. This database is used to estimate the degree to which workers are exposed to pesticides they handle, and ultimately to ensure that pesticides do not pose unreasonable risks to workers. The revised version allows the user to analyze a greater variety of exposure scenarios. In addition, OPP began a massive reprogramming of the database to make it more “user-friendly” and statistically powerful, as well as to incorporate much of the exposure analysis work being conducted in Europe via EUROPOEM, a European database.

OPP List of Chemicals Evaluated for Carcinogenic Potential. OPP has revised and made available electronically the *List of Chemicals Evaluated for Carcinogenic Potential*. This semiannual list provides an overview of compounds evaluated for carcinogenicity by OPP's peer review teams and various other national and international review groups, such as the World Health Organization.

Pesticide Adverse Effects Information Reporting/6(a)(2) Activities

Section 6(a)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires registrants to report to OPP any studies, incidents, or other information indicating new adverse effects of registered pesticides. This information helps OPP decide what action, if any, is necessary to reduce the risks posed by a particular pesticide.

Studies. OPP's 6(a)(2) Team screened nearly 600 adverse effects information submissions consisting of studies and preliminary reports of possible adverse effects. As a result of this screening, 15% of the submissions were determined to warrant expedited review. Of the 15%, one-third required no further action; 20% showed a new adverse effect which will be addressed by Special Review, an imminent reregistration decision, or risk mitigation negotiations; 17% are still in review; 14% resulted in label changes to reduce risks, mostly in cases of new findings in acute toxicity studies; 15% required more information; and 3% resulted in other actions such as new tolerances and voluntary cancellations.

Incidents. In 1995, OPP stepped up efforts to communicate with registrants on 6(a)(2) reporting requirements, which contributed to the substantial increase in pesticide incidents reported this year. OPP received approximately 1,435 6(a)(2) submissions containing more than 7,500 incident reports in 1995. To manage this data more efficiently, OPP is negotiating with several registrants on formats for aggregate, statistical reporting of less serious incidents. Analysis of incident data resulted in several risk reduction actions. For example, OPP used California worker poisoning data in requiring more stringent protective clothing requirements for products containing paraquat. Further, in the area of 6(a)(2) enforcement, EPA issued and settled a civil administrative complaint against DowElanco for failure to submit hundreds of reports of incidents associated with their registered products. The settlement included an agreement to submit additional adverse effects information and payment of a penalty of \$876,000.

Ecological Incident Monitoring And Reporting

OPP continued to broaden the scope of ecological incidents collected and reviewed in 1995. Since September 1994, 27% of the state agencies have reported incidents to OPP, up from 7% previously. Ecological incident data are useful in determining trends of effects that ultimately will provide information needed to reduce risk to nontarget species. The impacts on fish, wildlife and plants observed are valuable for confirming known or identifying unknown ecological risks associated with pesticides.

In 1995, OPP performed an analysis of the 700 ecological incidents evaluated to date. This analysis will be useful in designing future risk mitigation measures as pesticides are evaluated through reregistration and Special Review. Of the 78 types of uses with reported incidents, 48 were associated with agriculture, of which 20 were observed to have more than one incident. The highest number of incidents reported involved fish kills (34%), followed by bird kills (30%) and plant effects (18%). OPP has received reports of adverse effects to 270 species of birds due to pesticide exposure. The carbamates, a group of insecticides, appear to cause significantly more incidents of adverse effects to birds of prey and songbirds than other classes of pesticides. Ducks, geese, and other waterfowl appeared to be most affected by organophosphates, another class of insecticides. Some of the incidents appear to be caused by pesticide misuse, such as using a pesticide as an illegal bait to control coyotes that results in the death of birds of prey.

Information And Records Management Activities

When an applicant seeks to register a pesticide, all data related to that request must be logged, reviewed, indexed, and, if acceptable, microfilmed. Approximately 12,000 studies were subjected to this process in 1995. In addition, OPP received approximately 1,300 information requests for 4,600 files per month from its central collection of active pesticide regulatory case files. OPP also worked to properly manage the records reflecting decisions made on particular pesticide applications for future reference.

Human Resources Management

OPP's human resources efforts focused not only on the administrative aspects of personnel processing (including recruitment; processing of actions; providing guidance to OPP managers on policy, procedures, and regulations) but also on the development of OPP's employees. Key 1995 activities included leadership training for supervisors; ethics training for middle and upper level management staff; formal training for knowledge/skills enhancement and career development; and piloting a divisional information sharing program called "LINKs." LINKs provided a method for OPP divisions to share information on their functions and linkages to other divisions. In so doing, OPP divisions increased the understanding of how their activities fit within the overall OPP mission.

OPP also continued to participate in the Howard University Environmental Specialty Program (HUES). This program provides an opportunity for OPP support staff, primarily

composed of minorities and women, to prepare for a new career in the Environmental Protection Specialist series. Twenty-two students successfully completed the first year course work of the three year HUES Program. Twenty-five additional staff have are expected to participate during the 1995-1996 school year. In addition, OPP participated in the Howard University Academic Relations Program, which aims to develop talented minority candidates during a summer internship program and to enhance the relationships between the Agency and Historically Black Colleges and Universities.

Resource Allocation And Financial Management

OPP resources are allocated in three distinct phases: budget formulation, planning, and execution. During any given year, OPP is formulating a budget two years in advance, planning a budget for the upcoming year, and executing a budget for the current year.

Budget Formulation

Budget formulation is the process by which, on an annual basis, OPP develops what becomes the President's Budget that is submitted to Congress. In Fiscal Year (FY) 1995, OPP prepared the submission of the FY 1997 budget. In so doing, OPP worked with the Administrator's office to develop a budget that reflects Agency goals, objectives, and priorities. After approval by the Administrator, the FY 1997 budget was reviewed by OMB and ultimately will become the President's Budget. The budget is then subject to Congressional review. Ideally, the final budget is approved with the signing of the Appropriations Bill by the President prior to October 1 (the beginning of the new fiscal year).

Budget Planning

Each year senior OPP officials, Program Area Workgroups (made up of a cross section of OPP staff), and the resource management staff work together to develop the OPP Resource Management Plan. This plan identifies OPP's goals, objectives, and outputs for the upcoming year and the resources needed to accomplish them. In FY 1995, the resource planning process was streamlined, resulting in significantly less time and staff effort to develop the FY 1996 Plan.

For the FY 1996 plan, the OPP planning process tentatively allocated \$17.4 million for headquarters contracts and grants, \$3.5 million in headquarters administered regional grants, \$4.0 million in expenses, and \$55 million in salaries for approximately 760 employees. Nondiscretionary state grants and assistance, which are allocated outside of the OPP planning process, totalled approximately \$13 million.

Budget Execution

After the Appropriations Bill is signed by the President, the EPA Comptroller issues a new Operating Plan, which is executed by each Agency office. In executing the budget, OPP must carefully monitor expenditure of all funds, track compliance with budget plans, and coordinate appropriate Agency financial reports. During 1995, OPP obligated (spent) \$87 million dollars. These funds consisted of \$54 million in salaries and travel expenses for approximately 760 employees; \$19 million for contracts, interagency agreements, grants, and expenses; and \$13 million for grants and support to regions and states.

In 1995, OPP continued to collect several types of fees from pesticide registrants, which supplement Congressional appropriations. The collected funds consisted of \$2.5 million in tolerance fees, used to help support OPP's effort in establishing tolerances, and \$14.3 million in annual registration maintenance fees, used to help support the reregistration program.

The figure below indicates the approximate distribution of OPP staff effort to the six program areas. The figure is presented in terms of "Full-Time Equivalents" (FTEs). One FTE represents the number of hours spent by one employee working full-time for one year. Because some employees work part-time, or are hired or leave part-way through the year, the actual number of employees in any given year exceeds the number of FTEs. Many employees divide their time among different program areas.

1995 Staff Effort Per Program Area

Program Area	FTE
Registration	185
Reregistration	227
Special Review	66
Field Implementation and Communications	80
Policy, Regulations, and Guidance	73
Information and Program Management	119
TOTAL	750

In 1995, OPP expended approximately \$13.2 million allocated through the program area budget process. These “discretionary” funds were used for external contracts. The figure below shows how these funds were distributed among the different program areas. (Other major pesticide expenditures not reflected in this figure are travel expenses; salaries; and grants and other assistance to states, regions, and other organizations).

Funds Expended in 1995 By the Six Program Areas

Program Area	Funds
Registration	14 %
Reregistration	30 %
Special Review	3 %
Field Implementation and Communications	12 %
Policy, Regulations, and Guidance	21 %
Information and Program Management	20 %
TOTAL	100 %

Chapter 7: Biopesticide, Risk Reduction, and Reinvention Initiatives

For much of its history, the primary function of OPP has been to register and regulate pesticides, particularly chemical pesticides. In recent years, however, OPP has begun to shift from simply regulating pesticides to promoting systems of pest management that better protect health and the environment and enhance the quality of our lives. This approach recognizes that pesticides are only one element in controlling pests, and that in some cases non-chemical alternatives can be as effective as chemical pesticides with fewer health or environmental risks. Related to this shift in approach have been efforts to “reinvent” OPP's ways of conducting its work. This chapter summarizes OPP's accomplishments in 1995 in encouraging the introduction of a new generation of biological pesticides, reducing pesticide risks through environmental stewardship, and reinventing OPP organizations.

Creation Of The New Division

One of OPP's most important steps in adopting a new approach to pesticides and pest management has been the creation of a new division, the Biopesticides and Pollution Prevention Division (BPPD). Organized as a pilot in November 1994, the unit was established as a permanent division within OPP in September 1995. The division has assumed the registration and reregistration activities for biological pesticides, and also has the lead responsibility for the Pesticide Environmental Stewardship Program, which will be discussed later in this chapter.

Biopesticide Accomplishments

As with chemical pesticides, OPP is responsible for registering biologically-based pesticides, or “biopesticides,” used in the United States. The three major types of biopesticides that OPP registers are microbial pesticides, biochemical pesticides, and plant-pesticides. (Other biological pest control agents, such as insects that prey on crop pests, are exempt from OPP's pesticide regulations.) Microbial pesticides are bacteria, fungi, protozoans, and viruses used to control pests. Biochemical pesticides are naturally-occurring compounds that have a nontoxic mode of action to the target pest, such as insect hormones and pheromones (mating attractants) and plant growth regulators. As defined by EPA, plant-pesticides are pesticidal substances newly introduced into plants, along with the genetic material necessary for the production of the substances within plant tissues.

Because EPA believes that in general biopesticides are less hazardous than traditional chemical methods of pest control, the Agency has taken a number of steps to encourage their development and use. OPP's data requirements — that is, the types of studies that applicants must submit to register their new pesticides — and other regulations are tailored to the characteristics of biopesticides and, generally, significantly reduced compared to chemical pesticides. As a result, applicants can fulfill testing requirements and achieve registration more quickly and at substantially less cost.

In 1995, OPP registered a record 20 new biopesticides (see chapter 1 for a detailed listing), with processing times for new biopesticides ranging from three to 16 months. This registration time represents a substantial savings compared to traditional chemical pesticides. Some of the newly-registered biopesticides include:

- ▶ A strain of the fungus Beauveria bassiana. This fungus was registered to control the silverleaf whitefly, which has caused millions of dollars of damage to vegetable crops and cotton over the past five years. The fungal strain was also registered to control grasshoppers and related pests on rangeland, pastures, and various crops.
- ▶ A peach twig borer pheromone. This pheromone was registered to disrupt the mating of an insect known as the peach twig borer, a pest of a number of fruit and nut trees.
- ▶ Two strains of the bacterium Pseudomonas syringae. These bacterial strains were registered to control rot caused by several kinds of fungi during the storage of citrus and other fruits.
- ▶ Three plant-pesticides derived from the bacterium Bacillus thuringiensis, or Bt. In March 1995, OPP approved limited registrations for insecticidal substances produced by Bt and genetically transferred into corn, cotton, and potato plants. The products will help control a number of insect pests, such as the European corn borer, cotton bollworm, and Colorado potato beetle. OPP approved full commercial use of the Bt-potato pesticide in May and the Bt-field corn pesticide in August.

Piloting New Organizational Approaches

In addition to advancing new methods of pest control, the new division is serving as a pilot for testing new approaches to organizational structure and execution of work, such as those recommended in the Vice-President's report on reinventing government. The division is made up of multidisciplinary teams that manage all phases of registration and reregistration, including both risk assessment (scientific assessment of potential health and environmental risks) and risk management (policy decisions based on risks and benefits). The division is also testing a streamlined management structure that exceeds EPA's goal of an 11:1 staff to manager ratio. While adjustments continue to be made, many of the approaches have proved successful and will provide valuable lessons as EPA moves toward overall reorganization of OPP in 1996.

Promoting Integrated Pest Management (IPM)

Integrated Pest Management involves the carefully managed use of an array of pest control tactics — including biological, cultural, and chemical methods — to achieve the best results with the least disruption of the environment. IPM relies upon an understanding of life cycles of pests and their interactions with the environment. Biological control refers to using natural enemies of the pest, such as employing ladybugs to control aphids. Cultural control involves practices of cultivation, crop rotation, and other methods that prevent or control pests. IPM also involves the judicious use of chemical pesticides, if necessary.

OPP is involved in both urban and agricultural IPM. In the urban arena, OPP is providing the booklet, *Pest Control in the School Environment: Adopting Integrated Pest Management* and a companion training video to interested organizations. This year OPP worked with a consortium of outside groups to send this booklet and other materials on IPM to every school superintendent in the country. Projects related to IPM in the agricultural sector are described in the following section on environmental stewardship.

Pesticide Environmental Stewardship Program (PESP)

The Pesticide Environmental Stewardship Program (PESP) is a broad effort by EPA, USDA and FDA to work with pesticide users to reduce pesticide risk and use in both agricultural and non-agricultural settings. This program stems from a commitment made in September 1993 by the three agencies to:

- ▶ Promote the adoption of integrated pest management programs on 75 percent of U.S. agricultural acreage by the year 2000.
- ▶ Develop specific risk and use reduction strategies that include reliance on biological pesticides and other approaches to pest control that are considered safer than traditional chemical methods.

USDA assumed lead responsibility for the first goal, and EPA assumed the lead for the second, naming it the Pesticide Environmental Stewardship Program. PESP takes a four-pronged approach of public-private partnership, regulatory relief, research and demonstration, and education to achieve the goal of reducing the risk and use of pesticides.

The Partnership

The cornerstone of PESP is a public-private partnership approach, with pesticide user organizations working cooperatively with OPP. The partnerships are completely voluntary and entered into with the recognition by the federal government of the need for efficient, cost-effective pest control. Both the private sector Partners and the federal government make commitments under the program. Each Partner agrees to develop and implement an environmental stewardship strategy to reduce pesticide risk and use tailored to its own

circumstances. The strategies should contain specific pest management goals and emphasize reduction in the use of pesticides and a shift to less toxic methods.

When EPA, USDA and FDA announced PESP in December 1994, the following private organizations agreed to become charter Partners:

Agricultural organizations:

American Corn Growers Association	International Apple Institute
California Citrus Research Board	National Potato Council
California Pear Advisory Board	Pear Pest Management Research Fund
California Pear Growers	

Utility companies:

Appalachian Power	New York State Electric & Gas
Atlantic Electric	Ohio Power
Carolina Power & Light	Pennsylvania Electric
Columbus Southern Power	Pennsylvania Power and Light
Delmarva Power	Pennsylvania Rural Electric Association
Duke Power	Virginia, Maryland, Delaware Association
Indiana Michigan Power	of Electric Cooperatives
Kentucky Power	Wheeling Power
Kingsport Power	Wisconsin Public Service Corporation

The following organizations also subsequently joined as Partners in 1995:

California Cling Peach Advisory Board
 California Tomato Board
 Cranberry Institute
 Edison Electric Institute
 Golf Course Superintendents Association of America
 Mint Industry Research Council
 New England Vegetable and Berry Growers Association
 Northwest Alfalfa Seed Growers Association
 Pebble Beach Company
 Processed Tomato Foundation
 Professional Lawn Care Association of America
 Tennessee Valley Authority
 Texas Pest Management Association

PESP Partner organizations now represent more than 31,000 growers and 15,000 non-agricultural pesticide users. Many organizations that are not pesticide users have also expressed interest in supporting PESP; therefore, OPP created another membership category, Supporter, and plans to announce a group of Charter Supporters in early fiscal year 1996.

Partnership Commitments

Under PESP, the federal government commits to seek to promote and fund the adoption of alternative techniques and practices that enhance pest management and reduce pesticide risk and use. The federal government will also integrate the environmental stewardship strategies developed by Partners into its policies and programs for agriculture and the environment. Finally, the federal government will lead by example with its own use practices. Among OPP's activities in 1995 to fulfill this commitment were the streamlined registrations of biological pesticides described earlier in this chapter, as well as registrations of other reduced risk pesticides described in chapter 1. Also, the Department of Defense (DOD) signed a memorandum of understanding with OPP committing to reduce its pesticide use by 50 percent. DOD is a significant pesticide user on golf courses, runways, and in homes and schools located on military property in the U.S. and throughout the world.

Partners began making specific commitments in 1995. For example, the American Corn Growers agreed to promote and expand its "bottom-line" corn growing contest, which seeks to maximize a grower's profit while reducing production inputs such as pesticides. Utility companies committed to train their pesticide users in techniques to lower risks from pesticide application.

Grants and Demonstration Projects

Merely putting less-risky products on the market does not guarantee that they will be used. To encourage their use, the demonstration portion of PESP offers funding to investigate and demonstrate reduced-risk methods of controlling pests. These methods may include pesticides, cultural practices, management techniques, or mechanical controls.

In 1995, demonstration grants went to growers, regional EPA offices and PESP Partners. OPP and USDA matched funds to make available \$800,000 in a special call for proposals targeted to risk/use reduction of pesticides in 25 key commodities. Twenty awards were made to demonstrate reduced risk technologies on the following crops and sites: apples, citrus, cranberries, field corn, sweet corn, potatoes, tomatoes, alfalfa, and cotton; and in greenhouses, nurseries, highway rights-of-way, and landscaping.

Three EPA regional offices, Regions 5, 9, and 10, also received OPP funding. One project from Region 5 (which covers six Midwest states) addressed ultra-Low-Volume (ULV) herbicide application technology, a promising method for reducing application to one-half or less of label rates while still achieving comparable weed control. Region 5 also received funding to provide on-farm comparisons of the new generation lower risk pesticides with the

heavily used triazine herbicides. EPA's Region 9 office (representing the states of Arizona, California, Hawaii, and Nevada) is part of a broad pollution prevention partnership known as the Biologically Integrated Orchard Systems Project (BIOS). The State of California, almond organizations, and USDA are among the other participants in BIOS, which is reducing pesticide and nutrient applications on the \$600 million almond crop. This model information and technology transfer program is well suited to replication on other crops. Region 10, representing the Pacific Northwest, received funding for urban IPM programs for schools and public housing and to support alternatives to chemical pesticides for grasshopper control.

OPP also awarded seven grants, totalling \$260,000, to PESP Partners to assist in implementing portions of their stewardship strategies. These projects include education in expert systems, training and demonstration of IPM techniques, and development of new computer information systems.

To obtain a free brochure published in 1995 or other information on PESP, contact the toll-free INFOLINE at 1-800-972-7717.

Biological Pesticide Regulatory Relief

Over the past few years, OPP has provided regulatory relief to encourage the development and registration of insect pheromones, which can replace the use of certain chemical insecticides. OPP's 1995 efforts included expanding the allowable acreage from 10 acres to 250 acres for testing of certain pheromones without obtaining an Experimental Use Permit (EUP) from OPP. This rule applied to most types of lepidopteran pheromones (those designed to control butterfly and moth pests), including those tested for food crops, applied by any method at a low application rate. OPP also published a rule exempting these pheromones from tolerance requirements, meaning that crops grown during pheromone tests need not be destroyed, as is usually the case in pesticide testing. These regulatory decisions were expedited by comprehensive scientific submissions filed by the American Semiochemical Association, which represents the pheromone industry.

In May 1995, OPP issued a rule which, among other things, allowed agricultural workers to reenter areas treated with many biological pesticide products more quickly (after four hours) than previously allowed under the Worker Protection Standard. This rule will further encourage biological pesticides while still protecting agricultural workers.

Reinventing And Streamlining OPP's Organization

As part of the efforts to “reinvent” the federal government structure and to increase responsiveness, OPP has undertaken a number of streamlining projects. In addition to registration reinvention efforts and piloting the Biopesticides and Pollution Prevention Division, described elsewhere in this report, the most significant reinvention projects during 1995 were:

- ▶ Exploring new approaches to environmental risk assessment, including the creation of a multidisciplinary pilot branch on environmental risk characterization and interdisciplinary teams charged with developing options for reducing ground-water risks.
- ▶ Forming the OPP Streamlining Council, a forum in which OPP's managers and representatives of its staff can work together to address the issues and opportunities presented by the drive to reinvent and streamline OPP's organization and operations.
- ▶ Developing the OPP Reinvention Implementation Plan of March 1995 by the Streamlining Council, including the general design for a new divisional alignment. The plan was presented in draft to the full staff of OPP, and discussed in a series of open meetings. Hundreds of staff comments were received and reflected in the final version of the plan. The proposal was discussed extensively with industry groups, environmental groups, and other stakeholders, and refined to reflect some of their suggestions.
- ▶ Developing the full Reorganization Proposal of July 1995 by the Division Design Teams. These self-directed teams were formed to propose functional statements, work flows, and staffing patterns for each of the proposed divisions in the new alignment of OPP. Nearly 25% of the staff of OPP participated in the teams.

OPP's reorganization is scheduled to begin in 1996 but is contingent upon the status of EPA's budget. A number of other reinvention activities continued in 1995, such as completing a survey of customer satisfaction; performing an outside management review; piloting a continually updated, automated pesticide position file; and piloting non-supervisory, quality review teams for science issues. Comprehensive changes to the registration process are described in chapter 1.

How To Obtain More Information

The Office of Pesticide Programs (OPP) wishes to provide timely and consistent information to the public. If you would like additional information on subjects discussed in this report or other topics, here are some sources available to you:

OPP Public Docket — OPP's docket houses the regulatory notices, background documents and public comments on OPP activities. The Docket is open to the public from 8:00 a.m. to 4:30 p.m., Monday through Friday, and is located in Room 1132 of Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, Virginia (near the Crystal City subway station), telephone 703 305-5805.

Catalog of OPP Publications and Other Information Media — This catalog provides a listing of hundreds of pesticide publications, including science chapters, fact sheets, etc., and is available from EPA's Public Information Center, 401 M Street, S.W., Washington, DC 20460 (Telephone 202 260-2080); or the National Center for Environmental Publications and Information (NCEPI), P.O. Box 42419, Cincinnati, OH 45242-2419 (Telephone 513 891-6561 or Fax 513 891-6685).

Pesticide Regulation (PR) Notice 94-3 — This document provides general guidance for obtaining a variety of OPP records and publications. It provides key information and contacts for many resources available to the public (including Pesticide Dockets, Freedom of Information Act, the pesticide hotline, and on-line databases). Lists of OPP program contacts are included to help direct public requests regarding specific chemicals or policy issues. PR 94-3 can be obtained from:

Communications Branch, FOD (7506C)
Office of Pesticide Programs, U.S. EPA
401 M Street, S.W.
Washington, DC 20460
(703 305-5017)

Communications Branch — Recent announcements and copies of non-technical brochures and fact sheets on pesticide issues can be obtained from the Communications Branch, as listed above.

National Pesticides Telecommunications Network (NPTN) — NPTN, accessible by a toll-free telephone number, provides general information about pesticides and is available to anyone in the United States, Puerto Rico and the Virgin Islands (Monday-Friday, 6:30 a.m. to 4:30 p.m. Pacific Time) at 1 800 858-7378.

Electronic Availability of Pesticide Documents — Many EPA pesticide documents are available electronically from a variety of sources. Most of OPP's electronically-available documents, including *Federal Register* notices, press announcements, and Reregistration Eligibility Decisions (REDs), are available through the Internet. They can be accessed via EPA's World Wide Web server (<http://www.epa.gov>), EPA's Gopher server (<gopher.epa.gov>), or EPA's FTP server (<ftp.epa.gov>). Some documents can also be accessed through Fedworld (<fedworld.gov>). Reregistration and Special Review documents can be downloaded from an electronic bulletin board system, which can be reached via modem at 1 703 308-7224. A fact sheet describing these services can be obtained from the Public Docket, NCEPI, or the Communications Branch.

Pesticide Information Network (PIN) — The PIN is an interactive database system containing current and historic pesticide information. It is free and operational 24 hours per day, seven days per week. It can be reached via modem and communications software at 703 305-5919.

Pesticide Program Contacts

The following is a listing of OPP's senior managers as of October 1995, as well as the managers of OPP's parent office, the Office of Prevention, Pesticides and Toxic Substances (OPPTS). All OPP telephone area codes are 703.

Office of Prevention, Pesticides and Toxic Substances

Lynn R. Goldman, M.D., Assistant Administrator	(202) 260-2902
Susan H. Wayland, Deputy Assistant Administrator	(202) 260-2910
James V. Aidala, Associate Assistant Administrator	(202) 260-2897
Arnold E. Layne, Pesticide Program Advisor to the Assistant Administrator	(202) 260-2896

Office of Pesticide Programs

Daniel M. Barolo, Director	305-7090
Penny Fenner-Crisp, Deputy Director	305-7092
Marjorie Fehrenbach, Executive Assistant	308-4775

Policy and Special Projects Staff

Anne Lindsay, Director	305-7102
Paul F. Schuda, Deputy Director	305-7102

Biological and Economic Analysis Division

Allen L. Jennings, Director	305-8200
Susan M. Lawrence, Acting Deputy Director	305-8200

Biopesticides and Pollution Prevention Division

Janet L. Andersen, Acting Director	308-8712
Flora Chow, Acting Deputy Director	308-8712

Environmental Fate and Effects Division

Denise M. Keehner, Acting Director	305-7695
Evert K. Byington, Acting Deputy Director	305-7695

Field Operations Division

William Jordan, Acting Director	305-7410
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Health Effects Division

Stephanie R. Irene, Acting Director	305-7351
Debra F. Edwards, Acting Deputy Director	305-7351

Program Management and Support Division

Frank T. Sanders, Director	305-5440
Norman W. Chlost, Deputy Director	305-5440

Registration Division

Stephen L. Johnson, Director	305-5447
Peter P. Caulkins, Deputy Director	305-5447

Special Review and Reregistration Division

Lois A. Rossi, Director	308-8000
Richard D. Schmitt, Deputy Director	308-8000